

From DEPARTMENT OF MEDICIN, UNIT OF HEART AND  
LUNG DISEASES

Karolinska Institutet, Stockholm, Sweden

# **NEW INNOVATIONS TO SUPPORT SELF- CARE IN PERSONS WITH HEART FAILURE**

Eva Hägglund



**Karolinska  
Institutet**

Stockholm 2018

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Published by Karolinska Institutet.

Printed by E-Print AB 2018

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**ISBN 978-91-7676-930-0**

New innovations to support self-care in persons with  
heart failure  
THESIS FOR DOCTORAL DEGREE (Ph.D.)

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” Happiness is not the absence of problems but the possibility to deal with them”  
Shakyamuni Buddha

To all persons suffering from  
heart failure



# ABSTRACT

## Introduction:

Heart failure (HF) in combination with multiple chronic conditions is increasing rapidly, mainly in the elderly. Self-care is presumed to be one of the best practices for chronic illness including HF. Most of HF-related costs are attributed to hospitalizations with poor HF self-care as an important cause. The complexity of self-care leads to poor adherence to self-care. Mobile health (mHealth) and the use of technology has the possibility to support persons with HF and families to engage in self-care. Other strategies for improving self-care can be physical activities, known to improve cardiorespiratory and muscular fitness/strength, functional health, maintained cognitive function, reduction of anxiety and depression together with improved self-esteem. Self-care with yoga may be an alternative to exercise training and increase quality of life.

## Aim:

The overall aim of this thesis was to describe experiences and evaluate the effects of innovative self-care approaches such as the mHealth system and yoga among persons with heart failure.

## Methods:

The thesis is based on four studies using both quantitative and qualitative methods. Study I and II used an RCT design with follow-up assessment after three and six months including 82 persons with heart failure. The control group received care as usual. Data was collected using questionnaires before and after three and six months to determine the long-term effects on self-care, HRQoL, knowledge and hospitalization (I, II). To evaluate the experiences from the mHealth system a qualitative study with interviews were performed including 17 persons in study III. Study IV was conducted as a RCT study with 40 persons with HF, receiving either hydrotherapy or yoga. Evaluation before and after three months included HRQoL, six-minute walk test, sit-to-stand test, clinical variables, anxiety and depression.

## Results:

The mHealth intervention resulted in improved self-care, HRQoL and reduction in hospitalization days after both three and six months. Knowledge improved significantly after six months. Adherence to the mHealth system was high around 85%. Insight in the importance of adherence to self-care through daily weighing, was enhanced by the repeated reminder and instant feed-back from the mHealth system gathered from experiences. Technical adversities were common with a need of quick and easy support. Yoga and hydrotherapy had an equal impact on HRQoL, exercise capacity, clinical outcomes, anxiety and depression.

## Conclusions:

The mHealth tool strengthened adherence to weighing, improved self-care, HRQoL and reduced HF hospitalization days, together with improved HF knowledge after six months. Self-

care was obtained through understanding the deteriorating symptoms and signs, in connection to weight change and how to act. The experiences of mHealth could be determined in relation to “the situation specific theory of heart failure self-care”. Yoga could serve as a complement or alternative to exercise training such as hydrotherapy in persons with heart failure.

**Keywords:** Heart failure, self-care, mHealth, yoga, health related quality of life, depression, anxiety.



## LIST OF SCIENTIFIC PAPERS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals:

I. Hägglund E, Lyngå P, Frie F, Ullman B, Persson H, Melin M, Hagerman I. Patient-centered home-based management of heart failure. Findings from a randomized clinical trial evaluating a tablet computer for self-care, quality of life and effects on knowledge. *Scandinavian Cardiovascular Journal* 2015;49:193-99.

II. Melin M, Hägglund E, Ullman B, Persson H, Hagerman I. Effects of a tablet computer on self-care, quality of life, and knowledge: a randomized clinical trial. *Journal of Cardiovascular Nursing*. 2018 Jan 23. doi: 10.1097/JCN.0000000000000462. [Epub ahead of print]

III. Hägglund E, Strömberg A, Hagerman I, Lyngå P. Experiences of persons with heart failure using mHealth system for self-care with a tablet computer wirelessly connected to a weight scale-a qualitative study. Submitted

VI. Hägglund E, Hagerman I, Dencker K, Strömberg A. Effects of yoga versus hydrotherapy training on health-related quality of life and exercise capacity in patients with heart failure-a randomized controlled study. *European Journal of Cardiovascular Nursing* 2017;16:381-389.

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## LIST OF ABBREVIATIONS

CG	Control group
CRT	Cardiac resynchronization therapy
ECHO	Echocardiography
EEG	Electroencephalogram
EF	Ejection fraction
EHFScBs	European Heart Failure Self-care Behavioral Scale
ESC	European Society of Cardiology
HADS	Hospital Anxiety and Depression Scale
HF	Heart Failure
HFmrEF	Heart failure with middle range ejection fraction
HFpEF	Heart failure with preserved ejection fraction
HFrEF	Heart failure with reduced ejection fraction
HG	Hydrotherapy group
HRQoL	Health-related quality of life
IAYT	International association of yoga therapists
ICD	Implantable cardioverter defibrillator
IMT	Inspiratory muscle training
IG	Intervention group
IQR	Interquartile range
KCCQ	Kansas City cardiomyopathy questionnaire
mHealth	Mobil health
MI	Motivational interview
MR	Magnetic resonance
NDM	Naturalistic decision making
NTpro BNP	N-terminal pro-B natriuretic peptide
NYHA-class	New York Heart Association functional classification
PA	Physical activity
PCC	Patient centered care
PHQ-9	Patient Health Questionnaire-9
RCT	Randomized controlled trial

RPP	Rate pressure product
RT	Resistant training
SD	Standard deviation
SF-36	Short Form-36
6MWT	Six Minute Walking test
TM	Telemonitoring
VAS	Visual analog scale
VO2	Peak oxygen consumption
WHO	World Health Organization
YG	Yoga group



# 1 INTRODUCTION

## 1.1 PREFACE

Imagine a world where the treasures of knowledge could be left to those who comes after. Now we are not living in that world but instead in a reality with usual learning by experience. The art of self-care is partly due to the ability to learn, but also the experiences stored within us and the ability to transform it to a beneficial action. Habits are usually created early in life and it takes time to develop or change of a habit into something else. Usually it needs motivation to make a lifestyle change happen. That is where we in health-care have a role as motivators to those who seek knowledge and skills to make a change towards an increased self-care. With an increasing aging population, it will be an expanding number of persons suffering from heart failure (HF) often in combination with multi-morbidity. Many of these persons will look for symptom alleviation, seek knowledge and have a wish of participating in their own self-care. To improve outcomes by increased self-care in the growing population of persons with HF afflicting more than 38 million people in the world today is extremely valuable (1, 2). It has been estimated that the prevalence of HF will increase with 46% from 2012 to 2030, just to underline the magnitude and the urgent need for interventions to support self-care (3). This thesis aimed to study innovative approaches to new and old methods, with special focus on supporting self-care and wellbeing in persons with HF. It was made through testing an invention of a technological mobile health (mHealth) system and evaluated its effects on self-care, HRQoL, knowledge, adherence and hospitalization. Further through exploring the experiences from the persons with HF using the mHealth system. This thesis also wanted to evaluate HRQoL, physical exercise, depression and anxiety by the performance of yoga and hydrotherapy.

## **2 HEART FAILURE**

HF can be defined as a functional or structural impairment of the heart. This will result in reduction of the ability to deliver oxygenated blood corresponding to the requirement from metabolizing tissues of the body. Further, a reduced cardiac output and/or elevated cardiac filling pressures will appear during exercise but also in a resting condition. As a compensation to maintain sufficient cardiac output there is an activation of neuroendocrine hormones that includes the Renin-Angiotensin-Aldosterone system together with the sympathetic nervous system (4).

### **2.1.1 Etiology, epidemiology and prognosis**

In Sweden, the prevalence is estimated to be around 2-3 %. At the age of 75 years and older, about 10 percent of the population has HF (5, 6). Two percent of Sweden's total healthcare costs are related to HF and 75% of the costs are caused by hospitalization (5). The reasons for acute hospitalization for HF are varied, ranging from poor understanding of disease management, dietary, weight monitoring and non-adherence to medical therapy. The reasons can also be a failure to seek medical attention in time due to worsening HF by e.g. comorbidity of myocardial infarction, atrial fibrillation or anemia (7, 8). The most common causes of HF are related to ischemic heart disease and hypertension (6), valvular heart diseases and rhythm disorders such as atrial fibrillation (4, 5). HF is associated with a poor outcome including both high mortality and morbidity together with impairment and an exceptionally reduced HRQoL. One-year mortality is approximately 20-30%, while after five years it is around 50-65% (4). The long-term mortality rate for HF after diagnose has decreased in Sweden over the past two decades, but mortality remains high especially for persons who need frequent medical care, which is associated with a very poor outcome (9).

### **2.1.2 Diagnose**

A correct diagnose of HF and its etiology is very important and can be a challenge partly due to the unspecific symptoms and signs of HF (4). It is particularly difficult to detect early symptoms in elderly persons and those with obesity (10) but also among those with chronic obstructive pulmonary disease (11). There should be both symptoms and clinical signs together with a verification of impaired cardiac function through an echocardiography to confirm the diagnose (4). The echocardiography (ECHO) provides information about the anatomy and function of the heart, together with valvular function and estimation of the ejection fraction (EF). EF is the objective indicator of how well the heart is able to pump the blood throughout the body but is also an important prognostic marker (12). According



to European guidelines today (4), there are three different categories of HF. In the first category, the heart has reduced power of contractility, detected through reduced EF <40% and is called *heart failure with reduced ejection fraction* (HFrEF). The second category of HF has a preserved power of contractility with normal EF >50% but with reduced capacity to relax the heart and receive blood from the body and is called *heart failure with preserved ejection fraction* (HFpEF). A third category *heart failure with midrange ejection fraction* (HFmrEF) was recently formed as a distinct own category with the EF range between 40-49%. The new category should also have evidence of relevant structural heart disease such as left ventricular hypertrophy or left atrial enlargement, or signs indicating diastolic dysfunction. To be diagnosed with HF in one of the three categories, the persons should have blood samples with elevated levels of B-typical natriuretic peptides as well as symptoms and signs of HF (4). Another important investigation concerning HF is Electrocardiogram (ECG) which can give a picture of signs of hypertonia, previous myocardial infarction or rhythm disorders. A normal ECG means most likely that there is no HF (13). In summary, clinical findings, abnormal ECG or elevated B-typical natriuretic peptides levels are not enough to diagnose HF. ECHO of the heart is necessary where the size, pumpability, filling pressure, and appearance of the valves can be assessed (4).

### **2.1.3 Symptoms, clinical signs, NYHA class and comorbidity**

Symptoms are defined as experiences of illness from a subjective point of view reflecting the persons reality (14). The most common symptoms of HF are shortness of breath, exercise intolerance, fatigue, and ankle swelling (4). The symptoms in HF reflects the personal functional status and are classified into four stages based on symptom severity and how limited the person is during PA with respect to fatigue and shortness of breath and is related to self-care (15, 16). The reduced exercise tolerance is defined as New York Heart Association Classification (NYHA). Table 1 gives an overview of the most common symptoms of HF and what impact they have. NYHA classification places the person in one of four categories based on how limited they are by their symptoms during physical activity or during rest (17). Simultaneously there can be a multiple experience of combined symptoms and signs in HF (18). Three distinct symptom clusters are identified by Yu, Chan (19), *distress cluster* (including shortness of breath, anxiety, and depression), *decondition cluster* (fatigue, drowsiness, nausea, and reduced appetite), and *discomfort cluster* (pain, and sense of generalized discomfort). These clusters accounted for 63.25% of variance of symptom experience identified in persons with HF. All three symptom clusters independently predicted the

health related quality of life (HRQoL). Together with these symptoms there are usually difficulties in sleeping (20) together with reduced exercise tolerance and cognitive impairment (4, 19, 21).

**Table 1.** New York Heart Association of functional classification (NYHA) measuring

<b>Class</b>	<b>Symptoms</b>
NYHA I:	No limitation of physical activity. Ordinary physical activity does not cause symptoms/signs
NYHA II:	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in symptoms/signs
NYHA III:	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes symptoms /signs.  IIIa the person can walk > 200 meters  IIIb the person can walk < 200 meters
NYHA IV:	Unable to carry out any physical activity without discomfort and symptoms/signs during rest.

symptoms/signs of fatigue, dyspnea and palpitations.

Signs in HF are defined as objective biological changes by disease with the possibility to detect through different procedures like biomarkers and x-ray (14). Typical signs can be elevated jugular venous pressure and pulmonary crackles (18). Symptoms and signs may increase for several weeks, months or sometimes develop unexpectedly rapid, forcing the person to seek emergency care (18). It is very common in HF with comorbidities, defined as multiple concurrent conditions of other common diseases that also require active management (22-24). Comorbidity in HF is associated with increased age and there is a significant relationship between self-care and the numbers of comorbidities (25). There is considerable comorbidity among persons with HF together with ischemic heart disease, hypertension, diabetes and chronic obstructive pulmonary disease (26).

### 2.1.4 Health related quality of life

HRQoL has been identified as a clinical key indicator to predict morbidity and mortality in HF (12). Poor HRQoL is the strongest independent predictor of total healthcare consumption and costs. Healthcare costs in chronic HFrEF are at least two-fold higher than in the general population (27). Persons with HF experience a great impact on their HRQoL regarding physical reduction, but also depression and anxiety. HRQoL is a way of measure dimensions of life in relation to the person's reaction to his/her illness. The WHO definition of HRQoL consists of three components *physically*, *mentally* and *social*. It is of great importance to identify person-centered problems with measurements to improve the understanding of a problem and the person's subjective experience. Behaviors like genetic inheritance, and social factors throughout the life course appear to be more strongly correlated with the physical functioning and HRQoL in persons with old age (28). Highly prevalent impairments are not by definition perceived as severe by the person with HF and do not always contribute to the overall HRQoL. These insights are important in providing optimized, individualized care for persons with HF (29). Psychological distress, poor health perception, higher NYHA grading and lower education level are all identified as significant factors associated with around 50% poorer HRQoL (30). A recent review identified key factors associated with HRQoL and presented depression as the most frequent related factor leading to a worsening HRQoL, followed by a higher NYHA class, younger age and female gender (31). The measurement of health and sickness and the effects of the disease but also the impact of healthcare include an indication of change. The change is usually measured before and after treatment and estimates the perception of HRQoL and include the disease frequency and severity. Two basic categories of instruments are commonly used for different purposes and circumstances to measure treatment effects important to clinical management considering HRQoL. The first category contains *generic instruments* like Short-Form 36 (SF-36), and Euro quality of life 5 dimensions (EQ-5D) (32, 33), which are multidimensional and have an attempt to measure the core dimension of HRQoL by capturing the physical, mental, and general health, vitality and social condition. However, they may fail to capture small special effects within a disease and do not always respond to changes in specific conditions (34). The second category of instruments are those that focuses on these distinct aspects specific to the area of HF. These instruments are *disease specific* like Minnesota Living with Heart Failure Questionnaire (MLHFQ) and Kansas City Cardiomyopathy Questionnaire (KCCQ) (35, 36) and are sometimes perceived as more relevant than generic measures because of their ability to capture results and risk of deterioration and improvement through e.g. the symptoms in order to get an understanding of the individual's experiences living with the disease (36).

### 2.1.5 Treatment

Treatment goals in HF are reduction and facilitation of symptoms and signs, decrease hospitalization as well as improved survival. Furthermore, there is a conscious aspiration to improve HRQoL (2, 4). The European Society of Cardiology (ESC) has identified a standard care that everybody with HF should have access to, which involves basic treatment with adequate drugs, consideration of cardiac resynchronization therapy, advices of physical activity (PA) and good self-care (4, 37). The pharmacological treatment in HF is complex with a combination of medications and treatment-self-care strategies in an individualized composition simultaneously striving for optimal doses. Basic pharmacological treatment is angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) as alternative if intolerance to ACEI together with beta-blocker and mineralocorticoid receptor antagonist (MRA). Together with these medical treatments, different doses of diuretics are given to relieve symptoms and signs of congestion (4). Sacubitril/valsartan is a new available drug for the treatment of HF that may replace ACEI and ARB (38). If the person still is suffering from severe HF together with prolonged QRS duration, a cardiac resynchronization therapy (CRT) may be beneficial (39) alone, or together with an implantable cardioverter defibrillator (ICD) that can deliver an electrical shock to the heart when life-threatening rhythm disorders are detected (4, 40). Today it is common that a person with newly diagnosed HF is offered to come to a HF outpatient clinic. Pharmacological and self-care strategies are often given together with a multidisciplinary HF team, consisting of cardiologists and nurses, with access to a physiotherapist, dietician and social counselor (4). Jaarsma and Stromberg described the need for nurse-led HF-clinics based on nursing and reflected on the development over time with HF clinics as an important role in supporting persons with HF in self-care. Previously, it has been observed that follow-up visits to a HF clinic after hospitalization, improved survival, reduced number of hospital days and increased self-care (41, 42). An important addition to the aspect of care is person centered care (PCC) focusing on health and resources rather than disease and limitations. The model of PCC starts from the narrative of the person with HF and their view of illness and health and develop a partnership based on the co-relation with a personal health-plan (14).

### 3 SELF-CARE

Self-care is defined as a naturalistic decision-making (NDM) process addressing both the prevention and management of chronic illness, with the core elements of *self-care maintenance*, *self-care monitoring*, and *self-care management* (2). It is considered essential in chronic illness and practical recommendations for HF states the importance of support for self-care (4, 43). The self-care process is essential in the management of both health and illness throughout life (44). Self-care starts with individual responsibility, in making daily choices about preferred lifestyle. It is also a definition made by the WHO's Self Care Forum as "actions that individuals take for themselves, on behalf of and with others in order to develop, protect, maintain and improve their health, wellbeing or wellness" (45). Even if the definition can be expanded, to a process of maintaining health through health-promoting practices and managing illness (46) within that, there are a lot of circumstances that influences the performance of self-care. Self-care is a broad concept in which the person's behaviors affects the process regarding medication, diet, immunization, PA and the implementation of other lifestyle changes that correspond to the self-care recommendations to support an increased self-care maintenance (45, 47). There are underlying processes that make self-care complex, as the need for decision-making and always weighing thoughts, values and actions before choosing an approach (2, 43, 46). The choice of decision and behavior aims to maintain balance towards physical and mental stability and respond to symptoms and signs when they occur (43). Further, self-care is what persons do for themselves to establish and maintain health, prevent and treat illness which is dependent on many factors. Self-care is known to be affected by interaction of age, gender, cognitive ability, depression, NYHA class, HRQoL, socioeconomic factors as well as education. In the same time self-care is also based on values, past experiences and habits as well as the person's ability to use his / her knowledge and acquire new knowledge (16, 48). The very valuable source of interaction with family support is not to be forgotten in relation to self-care (49). In the guidelines of ESC there are advices on subjects that a person with HF needs to know about their sickness. At the same time, there are a lot of circumstances to consider affecting the possibility to carry out and implement self-care (37).

#### 3.1.1 Self-care theories

A theory can be defined as a logical set of verified relationships useful for explanation and prediction and thus for control (50). It is designed to describe a situation, explain how elements are related to each other in a specific situation, and can make predictions about the future. The self-care process has been investigated since the 1980s (44, 51) and has revealed as an extremely important part of a successful management of HF (2, 4, 43, 46). Based on

Orem's nursing theory (44), other self-care theories has been developed (46, 51), focusing on how specific clinical phenomena can be seen and understood in practice of HF like for example "the situation specific theory of heart failure self-care" (43).

### **3.1.2 Natural decision making**

The Naturalist decision making (NDM) is defined as a fundament to self-care, a way that everybody use their experiences to make decisions, but proper self-care can also be obtained through learning (47, 52). The NDM process reflects the complex and multifaceted procedure of the reality in life, where situations consists of an automatic, impulsive context (53). The NDM tries to understand the ability of humans and how a decision often involves uncertainty, time stress, misunderstanding information and dynamically changed conditions. It also affects the interaction between persons, by being situation specific towards the individual's problems. NDM is also influenced by individual experiences as well as interaction between environmental factors such as education and socioeconomic factors (43, 47).

### **3.1.3 Self-care maintenance**

The first part of the self-care process captures treatment adherence and healthy behaviors (43). A valuable aspect in the whole self-care process is this first category *self-care maintenance*, which is known to improve HRQoL, increase exercise capacity and reduce hospitalization and mortality due to outcome results (2, 54-56). To achieve maintenance, motivation and knowledge, together with effort are required to maintain optimal health in the best way, despite suffering from a disease. The changes may involve a lot of new medications prescribed. Other self-care behaviors in the process of maintenance is weighing daily, PA, immunization, to reflect on fluid intake, salt-restriction, managing stress, healthy heart-diet, smoking/ nicotine cessation together with how to handle alcohol (43, 46, 57). These self-care behaviors should be encouraged in order to make improvements in well-being but also to maintain health together with physical and emotional stability (43). The activities in the process of self-care can be chosen by the person him/her self to achieve created goals but also with the help of others, such as healthcare professionals or caregivers like partners/family.

### **3.1.4 Symptom-monitoring**

The second part of the self-care process starts with symptom perception as a part of *symptom monitoring*. Symptoms can be defined as a feeling of an abnormal experienced inner condition (53). The monitoring part involves body listening, detection, evaluation, interpreting the

meaning and labeling both symptoms and signs (43, 58). A reasonable action must be possible in response. The objective of monitoring symptoms and signs is according to Riegel and Jaarsma a recognition that a change has occurred (46).

### **3.1.5 Self-care management**

*Self-care management* is the part of the self-care process when the response to impairment of HF symptoms and signs may occur. This third part requires ability to manage symptoms and signs of deterioration, recognition of the change, but also to be aware of what action should be taken and how to handle it. If response is needed, self-care management involves the implementation of treatment together with an evaluation, so that the approach can be re-examined in the future (43, 46). All of the three parts in the self-care process are being influenced by both autonomous and advisory elements within the NDM process, affecting how a decision is created through influence by knowledge, skills, experience and values (43).

### **3.1.6 Self-care confidence**

Self-confidence is known to moderate and mediate the relationship between self-care and outcome (43). Cognition affects self-care behaviors in the process indirectly, through self-care confidence and interventions aimed to improve self-care confidence may improve the self-care process, even in persons with impaired cognition (59). Reflection or contemplation is linked to knowledge acquisition (60). Factors associated with self-care behavior are self-confidence, functional capacity, knowledge, health literacy and social support. The purpose of a study with 321 persons with HF was to explore factors associated with self-care behaviors and to examine the mediating role of self-care confidence. Associations found were that health literacy and social support were directly related to self-care maintenance. The results also showed that functional capacity and knowledge were directly associated with self-care management. Moreover, self-care confidence mediated the relationships between knowledge, health literacy, social support and self-care behaviors (61). Self-confidence both moderates and mediates the relationship between self-care and outcome (43) and there is a knowledge that cognition affects self-care behaviors indirectly, through the influence of self-care confidence. The result of improving self-care confidence may improve self-care, even in persons with impaired cognition. Self-efficacy can be involved as a mediator between effective self-care and self-confidence (59). Self-care confidence and information about maintenance and management of HF can give greater control of the health and encourages healthy behaviors which in the long term will prevent deterioration. In many cases persons can take care of their minor ailments, and by doing so reducing hospitalization (45).

### **3.1.7 Factors influencing self-care**

The self-care process has an overall significant impact on symptoms, well-being, prognosis and morbidity (37, 51, 62). Self-care in HF is affected by interaction of many different known factors such as age, gender, cognitive ability, depression, NYHA class, HRQoL, socioeconomic factors as well as education. In the same time the self-care process is also based on values, past experiences and habits as well as the person's ability to use his / her knowledge but also the dedication and effort of acquiring new knowledge (16, 48). The persons with HF are advised to take medication, follow restrictions, weighing, monitor symptoms and signs and manage their symptoms / signs in case of deterioration and perform a measure, followed by a proper evaluation (63). At the same time, they are also advised to maintain an optimal healthy lifestyle with for example PA and healthy diet. Poor adherence to HF recommendations is assumed to be responsible for approx. 50% of acute admissions to hospital due to deterioration of HF (64). Follow-up of both medical and non-medical treatments are crucial both for clinical survival and HRQoL.

### **3.1.8 Values motivation and culture**

Self-care is influenced by cultural beliefs, including the meaning ascribed to HF, and by social norms. A common belief from the persons with HF is that the sickness is inevitable or attributed to stress. There is also a belief from the afflicted persons that there is a spiritual link affecting the self-care concept in a way that prayers are believed to have an effect. Cultural beliefs have been supported by self-care behaviors like medication adherence. Cultural preferences can also affect the food choice even if salt-restricted diet is advised (65). A review of 19 qualitative research studies of a conceptual model of attitudes, beliefs, and expectations of persons with HF, showed that persons experienced a sense of disruption before developing a mental model of their sickness HF. The reactions when being diagnosed with HF includes becoming a strategic avoider, a selective denier, a well-intentioned manager, or an advanced self-manager. Persons with HF responded by forming self-management strategies and finally assimilated the strategies into everyday life seeking to feel safe (66).

### **3.1.9 Depression and cognitive ability**

A substantial proportion of persons with HF have concomitant cognitive problems. The prevalence of cognitive impairment in HF is around 43% (n = 26 studies, 4176 participants) according to a review of 26 studies (67). From a mental point of view depression is one of the most common causes of ill health and disability. Both depression and anxiety together with



impaired cognition are factors that affect perceptions and wellbeing in persons with HF (68). Depression has been detected in 13.9 to 77.5% in persons with HF (69-71). It is believed to be in such wide range due to multiple of symptoms simultaneously. Those with concomitant depression have two to three times higher mortality (72) and depression is considered to be an independent risk factor for mortality in HF (68, 69). Depression also has a significant prevalence with contributions to the overall poor disease specific HRQoL (73) by a strong relation to physical symptoms (74).

## **4 M-HEALTH TO SUPPORT SELF-CARE IN HEART FAILURE**

Today in society there is a trend towards increased use of technology in different combinations and forms. Partly due to the results of reducing morbidity and mortality in some of the studies, but also the improvement seen in self-care and HRQoL (4, 75). Although the results are unclear and as there are several types of mHealth and most are enrolled in multidisciplinary care management programs, each approach needs to be assessed on its individual merits.

A goal worldwide is to enhance the self-care process in persons with HF due to its major importance on outcome (37, 76). Technology in health care is an application for control and learning more about a disease together with health topics (75). There is a huge interest in technology with a comprehensive overall concept, eHealth concerning information and communication technology (ICT) (77).

### **4.1.1 What is mHealth?**

The concept mHealth represents a novel intensified follow-up strategy of HF management and may play a crucial role in early detection of HF progression and may improve outcome of persons with HF (78). A subdivision to ICT is mHealth including telehealth and telemonitoring. mHealth covers a broad spectrum from “mobile devices or hand-held computers such as mobile phones, laptops, tablet or PDAs, which can be used for text, voice or image communication, and can collect, process and report data”(77). Within the mHealth concept remote monitoring with or without transmission of physiological data is gathered. ECG, blood pressure, weight, respiratory rate and other self-care, educational or lifestyle advices are examples of such data. The information gathered can be stored within the technical device or transmitted to the healthcare by broadband, satellite, wireless or blue tooth (77, 79). mHealth can be used by the person himself who is suffering from a disease or in collaboration with the health care system or caregivers (75, 77). mHealth offers the person assistance in self-care, medical adherence and knowledge of when it is time to visit the healthcare (75). Even though two meta-analyses concluded positive results for mHealth showing a 34% decrease in mortality, together with a reduction of HF-related hospitalizations by 35-56% (80, 81) the difficulty in understanding and maintaining self-care behavior remains. It is still unclear whether the technological aids could provide concrete benefits for the self-care process in persons with HF and also in what form it should be delivered (77). There are a lot of circumstances that affect the abilities to perform and enhance self-care through

mHealth (37, 82). Up to date the impact of the mHealth-based HF interventions on HF-related outcomes are mixed (83). A newly published review of nine studies where six were randomized controlled trials, illustrated the impact of mHealth interventions on all-cause mortality, cardiovascular mortality, HF-related hospitalizations, length of stay, NYHA class, left ventricular ejection fraction, HRQoL, and self-care showing the overall impact on current mHealth as inconclusive which underscore the need for further research to enhance the self-care process (83).

#### **4.1.2 Adherence to mHealth and the self-care process**

Adherence to the use of the mHealth system is usually high, demonstrated by Seto and Leonard (84) with 70% of IG who completed at least 80% of their possible daily readings. Hoban and Fedor observed that adherence with weighing after six-months follow-up was the same in IG with mHealth and CG(85). Boyne and Vrijhoef also reported that daily weighing improved after three months together with fluid intake but also daily PA. Adherence to medication increased after six and 12 months but no effects on diet, smoking and alcohol consumption occurred (63). Lynga and Persson also observed in their study that the average personal adherence to daily weight was high in IG with mHealth. Persons with adherence > 60% to daily weighing were hospitalized less than persons with <60% adherence for cardiac event, although this was not statistically significant (86). In a pilot-study of Arinian and Harden the persons in the IG group had high adherence to medication, which turned out to be 94% (87). Their study with mHealth also showed 81% daily blood pressure measurement and 85% adherence to daily weight in comparison with CG group. Ramaekers and Janssen-Boyne observed in their study of adherence that fluid retention, daily weighing, physical exercise and alcohol restrictions significantly improved in IG with "Buddy mHealth" compared to CG. Medical adherence showed no significant difference in the RCT of the three groups studied by Wakefield and Holman neither at three or six months follow-up time (88). In Boyne and Vrijhoef study (63), self-care measured by EHFSBs was improved by mHealth, while no changes were made to persons receiving common care. On the other hand, in Bowles and Riegel study, there was no significant effect on self-care compared to standard home care measured by Self Care HF Index regarding self-care maintenance, self-care management or self-confidence with respect to HF self-care (89). Improvement for both IG and CG was seen within groups comparison of both self-care maintenance and self-care management in Seto and Leonards (5) study, while self-care maintenance was more enhanced in IG. A multicenter study (n=314) with mHealth evalu-

ated by EHFSBs a significant difference in self-care was between IG and CG (90). Ar-tinian and Harden performed a small RCT pilot-study with 18 persons with HF using the EHFSB scale looking at self-care behavior and detected no differences between IG and CG after three months using mHealth (87). Hoban and Fedor detected after 90 days a significantly improved self-care management between IG and CG. After 60 days, an increase in PA was observed, which was not seen after 90 days (85). In the study by Dansky and Vasey (91) the IG group with "Buddy mHealth system" was evaluated and significant improvement was detected in 5 of the 8 self-care areas. The five areas were flexible diuretics in breathlessness, flexible diuretics in edema, flexible diuretics at weight gain, daily weight and current weight. IG and CG showed no differences between groups concerning current salt intake, filling in doses with medication and adherence with medication. Benatar and Bondmass had also evaluated the mHealth system "Buddy mHealth" in a RCT study. Care was delivered by the home nurse visit or nurse visit+mHealth. Differences was discovered in the use of salt in cooking with a decrease for those using mHealth (92).

#### **4.1.3 mHealth and self-confidence**

Self-esteem in HF, measured with Efficacy expectation scale in 382 persons with usual care in CG compared to IG with mHealth, showed significant improvement at six months in IG but not after 1 year (63). Also in the study by Benatar and Bondmass, self-esteem was measured but by the Self-efficacy scale in being able to feel safe in managing the disease of HF, a significant increase was demonstrated in the IG group receiving mHealth (92). Several studies (93, 94) explore the "Buddy mHealth system" using the Efficacy expectation scale regarding self-esteem in HF disease management and reported significant differences between IG and CG. Wakefield and Homan (88) had three groups of persons with HF in their RCT study, a telehealth group, a video group and a standard CG. There were no significant differences between the three groups studied with two of the instruments that focused on self-esteem and symptom-monitoring.

#### **4.1.4 mHealth and disease-specific knowledge**

Disease-specific knowledge was significantly higher in IG than CG in a multicenter study evaluating mHealth (n=314) (90). This was also seen in the study of Boyne and Vrihoef where HF knowledge improved significantly between CG and IG using mHealth (63). Delaney and Apostolidis (95) saw that both CG and IG with mHealth increased their knowledge in HF from baseline to 90 days. Wakefield and Holeman could not detect any difference in measuring the disease-specific knowledge between IG and CG with mHealth (88). On the other hand, Ramaekers and Janssen-Boyne could measure an improvement that was

significant in disease-specific knowledge in two of the three hospitals where the study was conducted, using mHealth (96).

#### **4.1.5 Barriers to mHealth**

Barriers to mHealth are described as, lack of immediate benefit in using the mHealth system, the mixtures of symptoms related to comorbidity in elderly, compatibility and perceived lack of security. Further, the need of simple usable technology together with training due to lack of computer skills and low self-efficacy. Other limitations mentioned are forgetting to use, concentration problems, and visual or cognitive limitations in elderly (57, 97, 98). There are other barriers from the health organization and professional point of view due to conflicting evidence but also the time and education issue in building new experiences to work efficiently with mHealth (57).

## 5 PHYSICAL ACTIVITY AND SELF CARE

Physical activity is an important part of self-care and there is a great interest to improve and intensify PA in persons with HF (2). New physical training methods to increase and individualize PA, based on personal preferences are needed for improvement. Today there is a common knowledge that low PA contribute to lower capacity found in persons with heart diseases (99). HF-action, the largest randomized controlled trial to date on PA in HF (n=2331) showed a modest improvement in exercise capacity and mental health in those who were physically active. The adherence to the prescribed regimen of PA after three years was only 30% (100) which strengthens that alternative forms of PA are needed.

### 5.1.1 Definition of physical activity

PA can be defined as “any bodily movement produced by skeletal muscles that results in energy expenditures” and is highlighted as a key component to enhance the experience of well-being. PA can either be classified as structural or incidental. Structural activity or exercise is a planned and purposeful activity to promote health and fitness benefits. Incidental activity is PA that are unplanned (101). When assessing PA there are four dimensions included in the concept. First dimension is mode or *type of activity* in which a description of type of activity performed e.g. waking, gardening, cycling etc. should be made. It can also be defined in the context of physiological and biomechanical demands/types e.g. aerobic versus anaerobic activity, resistance or strength training, balance or stability training. Second dimension include the *frequency* in number of the performed activity. Third dimension defines the *duration* in time of the performed activity. The fourth and last dimension is the *intensity* in rate of energy expenditure of performed activity. It is an indicator of the metabolic demand of an activity (102). Summarizing, the goal when presenting PA is to identify the *frequency*, *duration*, *intensity*, and *types of activity* performed during a time-period range from a few hours to a lifetime (103). In addition to the dimensions are four common domains in which the PA occurs, central for understanding behavior change in assessment of PA. First domain is *occupational* e.g. carrying or lifting objects at work. Second domain is *domestic* e.g. housework, yardwork, childcare, self-care, shopping, incidental, transportation and leisure time. Third domain named *transportation* include e.g. walking, bicycling or climbing. The last and fourth domain is *leisure time* e.g. sports, hobbies, exercise (102).

### **5.1.2 Benefits of physical activity**

Measures of PA can be assessed subjectively by self-reports as questionnaires and diaries. Direct measures can be made with objective methodologies like motion sensors such as accelerometers, pedometers, heart-rate monitors, and multiple-sensor devices. There are also different methods used to quantify energy expenditures. Relative intensity of PA can be determined in relation to exercise capacity like peak VO<sub>2</sub>, percent of peak heart rate or six-minute walk test (6MWT) (102). Engaging in PA during life has many benefits, including increasing life-span. A recent pooled analysis of large longitudinal studies found that persons who engaged in 150 minutes per week of PA at moderate intensity had a 31% reduction in mortality compared with those who were less active with the greatest benefit for those older than 60 years (104). PA has multiple other benefits in older age including improved physical and mental capacities. There is a 50% reduction in the relative risk of developing functional limitations among those reporting regular and at least moderate-intensity PA. The benefits known by increased PA are improved cardiorespiratory and muscular fitness/strength, bone and functional health, maintained cognitive function, reduction of anxiety and depression together with improved self-esteem (105-107). PA also appears to preserve, and may even improve, cognitive function in persons without dementia (105, 108) together with reduction in cognitive decline by around 30% (109). Yet, despite the clear benefits of PA, the proportion of the population meeting recommended levels falls with age, and analyses of data from SAGE and the WHO World Health Survey suggest that around one third in age 70–79 and one half of persons aged 80 years or older fail to meet basic guidelines for PA (110).

### **5.1.3 Recommendation of physical activity**

Persons are considered physical active if they perform more than 30 min/d of PA with minimum modest intensity, equivalent to approximately 10000 steps/d. according to Tudor-Locke and Basset criteria (111, 112). According to the WHO, PA for adults aged 65 years and above are recommended for at least 150 minutes of moderate PA per week or 75 minutes of vigorous PA. The activity should be performed in periods of at least 10 minutes duration. There is a dose-response relationship which increases with PA time. In addition, muscle-strengthening activities, involving major muscle groups, should be done twice a week. Older with poor mobility, are advised to add activity to enhance balance and prevent falls three days per week. PA should always be encouraged within the framework of abilities and conditions (107) also strengthened by Wahid and Manek (113) suggesting that the greatest health-benefit is associated with moving from inactivity to small amounts of PA. A total of 36 studies (n=3 439 874)

and 179 393 events, during an average follow-up period of 12.3 years were included in that analysis.

#### **5.1.4 Exercise training**

Exercise as a therapeutic intervention is defined as “physical activity that are performed repetitively to increase the performance capacity of the cardiovascular system (*aerobic exercise training*) or muscular skeletal system (*resistance exercise training*)” (54, 101). Even moderate exercise training shows significant improvements in self-reported health status with KCCQ measuring disease specific HRQoL compared with usual care without training. Improvements shown in the study by Flynn, Pina (100) occurred early and persisted over time performed with 2331 medically stable persons with HF. In HF physical exercise training is a part of self-care and is well established and documented with recommendations in guidelines (4, 114). Results from systematic reviews and meta-analyses have shown that exercise training is not only safe but also associated with reduced risk of hospitalization and decrease in mortality (55, 56). Many randomized controlled trials have shown similar benefits (105, 115) with progressive resistance training and may give independent benefits (116) together with benefit in HRQoL for persons with HF (117).

##### *5.1.4.1 Muscle strength, endurance and balance*

Interventions to promote muscle strength and endurance have also been shown to be effective for improving physical functioning in older people, including improved strength (116). All domains of PA and exercise training are essential for the older population such as aerobic, strength and balance. Aerobic exercise are well investigated, however new evidence shows that progressive resistance training (RT) has favorable effects not only on muscular strength but also on physical capacity and the risk of falls (116). These benefits can be extended to cardiovascular function, metabolism and coronary risk factors (17) for those with or without cardiovascular disease. In a study by Giuliano and Karahalios with RT as a single intervention they found increase in muscle strength, aerobic capacity and HRQoL in persons with HF (118). RT may offer an alternative approach, particularly for those unable to participate in aerobic training. The effect of RT on muscle strength is mainly during slow controlled movements (118). Aerobic training has shown reversed left ventricular remodeling in clinically stable persons with HF but this benefit is not confirmed with combined aerobic and strength training (119). Anyhow, endurance training with or without strength training is recommended for clinically stable persons with HF and is associated with an improvement in peak VO<sub>2</sub>, muscle strength and HRQoL. It also reduces overall and disease-specific hospitalizations (54, 120, 121). In a study performed by Davis et al. 3647 persons with HF, mainly male, with



low-to-medium risk, and NYHA class II-III with a EF of <40% were compared with usual care. Exercise training reduces HF-related hospitalizations and resulted in clinically important improvements in HRQoL. Concerning HF medication it should be optimized with the awareness that ACE inhibitors have a moderate positive effect on the working capacity (122). An increase in work capacity and EF both in rest and after exercise is expected with the treatment of beta-blockade (123).

Hydrotherapy improves exercise capacity as well as muscle function in small muscle groups in persons with HF together with increase in HRQoL. Hydrotherapy has shown a general increase in early diastolic filling accompanied by a decrease in heart rate, leading to an increase in stroke volume and EF (124-127). Today hydrotherapy is implemented as an alternative to physical exercise training in standard HF care in the Swedish population (128).

### **5.1.5 Adherence to physical activity**

The WHO 2015, definition of adherence is the extent to which a person's behavior—medication, following a diet, and/or executing lifestyle changes—corresponds to the recommendations of a healthcare provider. Non-pharmacological treatment of HF includes self-care education for the person with HF together with the family or caregiver. To be adherent to medication, PA, vaccination, fluid restriction and daily weight often requires an effort by the individual/person with HF (37, 57, 86, 102). Five dimensions that affect adherence consists of *social* and *economic factors*, factors related to the *health care system*, to the *condition of the person* and the *therapy* (129). Analysis has showed that self-efficacy and cardiovascular risk factors are related to adherence (93). A correlation with adherence and factors regarding marital status, education and income, related to self-care results have arisen in other studies (82). Adherence to physical exercise in HF is around 50% (100, 130, 131). Non-adherence to exercise recommendations has effects on clinical outcome such as increased HF readmission and mortality (129, 130). In addressing adherence to application of exercise recommendations there are aspects that need consideration, like the adherence to self-care PA advices, but also health care providers adherence to clinical guidelines (132). Exercise adherence is the extent to which a person acts in accordance with the advised interval and exercise dosing regimen given (102, 103). Various management programs aimed to optimize self-care in HF have been launched and evaluated, but still there are difficulties to comprehend and maintain self-care in PA recommendations. Despite PA being safe, effective, and a guideline-recommended treatment to improve HRQoL, exercise training remains underutilized. Both the person him/herself, the practice and environmental barriers need to be addressed to improve this

quality gap (4, 114). Older age, a low level of education together with socioeconomically disadvantaged are known factors influencing adherence to rehabilitation and PA in general (133, 134). To perform regular PA throughout the whole life requires motivation and effort. Persons with HF is known to have positive outcomes such as improved physical capacity and HRQoL, and reduced health care utilization with regular exercise training (132). Exercise limitation is characteristic in HF and increasing degree of intolerance is associated with poor prognosis (130). There are a lot of circumstances that correlates in different ways to low PA in adults, like demographic and biological factors, psychological, cognitive and emotional factors. Also, behavior attributes and skills, social and cultural, together with physical environmental factors (110, 135).

### **5.1.6 Barriers to physical activity**

Some of the factors influencing PA concern personal factors, lack of time, knowledge, and motivation (106, 110). Physical appearance concerning fatigue, anxiety/depression (130) or comorbidities (136) but also the cost of exercise facilities influences PA. Higher NYHA classification and a lower self-efficacy are other factors associated with less daily PA (111). Detection and addressing the barriers by using for example motivational interviewing (MI) are of great importance. MI is demonstrated to improve PA leading to energy expenditure increase between 26-37 % in two studies compared to control (137, 138). Barriers in persons with HF also include lack of time and is related to suffering from minor injuries or feeling physically tired. The psychological motives seem to be the utmost reason to perform PA. The wish of being healthier and live longer but also to slow the aging process and feel younger is experienced by 50%, rating physical and social motivations as least important (139). The challenge with PA and evaluating new PA in HF is to understand the concomitant lack of adherence (140). Klompstra et al. found in their recent study on exergaming in persons with HF that exercise self-efficacy had a role in explaining the relationship between motivation and PA and may therefore affect adherence to recommended PA (139). Self-efficacy can be developed through realistic goal-setting, supervised exercise training and support (141). Performing PA as suggested in HF guidelines remains low for both male and female (132) but females seem to have a higher motivation than men (139). Comorbidity by coronary diseases is to be considered as present in more than 60% of person with HFpEF and HFrEF and careful evaluation during exercise is needed concerning exercise limitation due to impaired cardiac reserve (142).

### **5.1.7 To influence physical activity**

Education has been identified as an opportunity to improve a person's ability to perform self-care (143, 144). Evidence based recommendations are stated in European guidelines, what a person affected by HF needs to know about their sickness for optimal self-care (2, 4, 37). The persons are urged to register the weight daily and respond to weight gain of > 2-3 kg, which should lead to an increase of diuretics for 3-4 days, but also the evaluation of the expected weight loss and decrease of the symptom burden (41). The self-care councils that are disease-specific and gives non-pharmacological treatment also include the importance of smoking cessation as well as reduction of alcohol consumption, sexual counseling and finally a low-fat diet (37). The level of education found in Klompstra et al study was significantly associated with the levels of PA. Persons performed high PA had higher exercise self-efficacy and higher exercise motivation compared to those with a low PA level. No differences were found between those with a high PA level towards a low regarding gender, NYHA classification or comorbidity (139). Problems in the HF self-care process concerning knowledge has been analyzed in relation to neural alterations associated with HF. As a neural process, decision making has been traced to regions of the prefrontal cortex, the same areas that are affected by ischemia, infarction, and hypoxemia in HF. This in turn leads to deficits in memory and attention but also may impair the perception and interpretation of early symptoms and signs of deterioration in HF (143). Reflection or contemplation is linked to knowledge acquisition (60).

### **5.1.8 Support from society, health-care and caregivers**

Education, counseling and learning skills always need additional development and improvement as life and circumstances constantly changes. Together with caregivers that take an active part in home-based interventions, support can improve outcomes by strengthening the ability to self-care (145). For the caregiver there is also a lot of related factors found that affect the caregiver burden over time. Liljeroos et.al found that when the person with HF was younger, had less comorbidity, higher level of perceived control, physical health and less symptoms of depression resulted in a better health in the caregiving partner (49). The family caregivers expressed a need for patience, as well as a compassionate way to cope with frustration. They expressed that personal qualities such as compassion, thoughtfulness and understanding were considered essential requirements in the caregiving role (146). HF often requiring in-hospital care but also at home-based care in different periods of the sickness. Educational interventions targeting the socio-cultural influences of the person with HF together with their caregivers through a structured and well-designed program may improve outcomes

(147). Important motivators for PA in adults include advices from health care providers. There is also a concern from persons about the safety, lack of facilities nearby, weather concerns or shortage of sidewalks or places to sit and rest. It is also a concern of responsibilities within the family or caregivers, not to forget those, with a lack of social support concerning PA (110, 148). In HF there are no differences found in potential barriers between men and women concerning PA (139). Conducting in-depth interviews with 35 adults on average of 67 years of age, they described existing barriers and facilitators to neighborhood-based activity with mobility disabilities. Preparing the neighborhood environments for an aging population that uses assistive devices is important in the future (149). However, persons also described that performance of PA needs to be purposeful and fun (148). A review made of 31 studies also supported the fact that there is a relationship between the physical environment and PA among older adults (150).

## 6 YOGA TO IMPROVE HEALTH RELATED QUALITY OF LIFE

Yoga therapy is difficult to define, partly because the discipline can be approached in many ways, both in respect to traditions but also by compositions and intensity of postures and different meditations. A reasonable and pragmatic understandable statement in defining yoga is set by the International Association of Yoga Therapists (IAYT) as "yoga therapy is the process of empowering individuals to progress toward improved health and well-being through the application of the teachings and practices of yoga" (151). Asia is origin of yoga from ancient times, many thousands of years ago. Yoga originated as a philosophical or spiritual discipline to deliver practitioners from suffering and is defined in Sanskrit as "to join" (152). The autonomic nervous system regulates the parasympathetic and sympathetic systems and influences functions such as digestion, heart rate, and respiratory rate as a compulsory stabilizing response to stress and other environmental challenges (153). Yoga can be described as a body and mind therapeutic intervention that includes a lifestyle aspect. Yoga has been used for persons with depressive disorders and elevated levels of depression (154, 155) and is suggested as a treatment option for persons with HF. Yoga is especially characterized to achieve mental, emotional and physical balance of sentient beings (156-158). Treatment of yoga includes breathing exercise (pranayama) (159), postures (asanas) (160) and meditation (dyana) (161, 162). Meditative music is usually played during parts of the sessions of yoga (163).

### 6.1.1 Yoga breathing (pranayama)

The yogic breathing technique of *pranayama* involves many different techniques but the most common is the slow deep breathing inspired with the predominant use of the abdominal musculature and the diaphragm. The breath is held momentarily in full inspiration within the limits of comfort and allowed slow and spontaneous exhalation (164). Several factors contribute to the reduced exercise tolerance that has been identified in persons with HF, including alterations in central hemodynamics, skeletal muscle oxygen utilization and respiratory muscle dysfunction (165). Respiratory, or inspiratory muscle training (IMT) has shown potential beneficial effects in persons with HF such as improved peak VO<sub>2</sub> (166). Smart et.al conducted a review on eleven studies containing data on 287 persons with HF performing IMT compared to control. Respiratory muscle training improved cardio-respiratory fitness and peak VO<sub>2</sub> and showed better results in the functional 6MWT together with an increase in HRQoL (167). Another study indicate that IMT improves cardio-respiratory fitness and HRQoL to a similar magnitude as conventional exercise training (121). Ekman and Kjellström investigated if lowering breathing rate with the help of a respiratory modulation (RM)

twice daily or listening to music for four weeks could improve breathlessness and NYHA class in persons with HF. RM resulted in having a potential to relieve symptoms of HF by changing the breathing patterns together with an improved NYHA class (168). Baroreflex sensitivity is a measure of the heart's capacity to efficiently alter and regulate heart rate and blood pressure in accordance with the requirements of a given situation. A high degree of baroreflex sensitivity is thus a good marker of cardiac health (169). With a multitude of different breathing techniques in yoga, slow breathing consisting of equal inspiration and expiration seemed to be the best technique for improving baroreflex sensitivity (159, 170, 171). Contrary, Mason et.al suggested in their study that practitioners of yoga can engage in a ratio that is personally comfortable and achieve the same benefit of the baroreflex sensitivity (172).

### **6.1.2 Yoga postures (asanas)**

Yoga essentially involves the adoption and maintenance of certain simple to complex body *asanas*. Yoga movements are usually a combination of physical moves aimed for balance of energy disturbances in body and mind. The asanas can be performed sitting, lying or standing and performed in different combination postures. The asanas consists of a combination of forward, backward and sideward bends, twists and balance poses individually modified according to medical or orthopedic limitations if needed from the body. Jayasinghe (164) describe that the ancient practice of yoga has notes that contains 840 000 asanas. Of these only some are recommended to be useful for regular practice. The common advice for each asana is to be maintained for a period of 5–20 breaths.

### **6.1.3 Yoga meditation (dyana)**

Meditation can be described as a combination of complex emotional and attentional regulatory strategies developed for various reasons, including the cultivation of well-being and emotional balance (173). Two different parts of *dyana* techniques are usually combined, *focused attention meditation* with or without mantras "instruments of thoughts" and *open monitoring meditation*. The goal of these meditations is to reach a state in which no explicit focus on a specific object is retained by remaining attentive moment-by-moment to anything that occurs in the mind (174, 175). The potential regulatory functions of these practices on attention and emotion processes can have a long-term impact on the brain and behavior (173). Meditation is thinking of nothing or rather not thinking of something and is a challenge to balance. The concentration or rather relaxation of mind is dependent on the ability to resist distractions from the outer and inner world and control of their impulses and emotions. Meditation may involve an internal effort of self-regulating the mind (173, 176, 177). A review of

nine studies investigating the effect of meditation, seven demonstrated improvement in symptom relief. Relaxation, meditation, guided imagery, or a combination of these strategies resulted in less dyspnea and better sleep compared with attention control or usual care. Meditation also reduced pain, dyspnea, fatigue, and sleep disturbance within the treatment group (162). There are numerous scientific research in assessing potential health benefits of various types of meditations as in e.g. neuroscience, meditation induces neuroplasticity in the brain (178) which allows the neurons (nerve cells) in the brain to compensate for injury and disease and to adjust their activities in response to new situations or to changes in their environment (174). It is the brain's ability to reorganize itself by forming new neural connections throughout life. Recently, meditation has been explored with quantitative parameters by Bhaduri et.al using instantaneous heart rate in beats/minute. The cardiac dynamics during meditation was measured during performance of Kundalini yoga or Chi meditation. The cardiac dynamics changed in complexity supporting that these techniques could affect physiological responses during meditation (179). A novel study in the area of HF is the evaluation of mindfulness-based interventions with promising results significantly reducing the self-reported impact of fatigue, symptoms of unsteadiness/dizziness and breathlessness/tiredness related to NYHA class (180).

#### **6.1.4 Yoga music**

Another novel area of science is the content of yoga music and its influence in the brain. Maity et.al present data regarding neural activation of the alpha and theta brain wave through EEG rhythms while listening to simple acoustical stimuli. The findings showed spectral width showing that the complexity of alpha and theta rhythms increased in all the seven frontal locations in the brain studied, as an effect of musical stimuli. This led to a quantification of emotions using multifractal spectral width as a parameter to be used in cognitive music therapy (181).

#### **6.1.5 Effects of yoga**

Yoga has been reported as an effective modality in improving various physical and psychological aspects of elderly populations, and in the review by Patel et.al of 18 studies with 649 older adults they suggested that yoga may be superior to conventional PA interventions in elderly persons concerning self-rated health status, aerobic fitness, and strength but the evidence was mixed for yoga's effect on depression and sleep (182). Mooventhan & Nivethitha concluded in their recent review of elderly individuals that regular practice of yoga can be considered as an effective intervention of improving physically, through reduces heart rate, blood pressure, blood glucose, oxidative damage, reduced fatigue and weakness. There was

also a decrease in the fear of fall, and improvement of heart rate variability, baroreflex sensitivity, insulin sensitivity, physical functions, mobility, flexibility, and urinary incontinence. Further, there were mental effects through reduced anxiety and depression. Emotionally evaluated through reduction of anger, stress, tension and improved self-efficacy. The social benefits showed improved life satisfaction and vitality together with offering a better quality of sleep and HRQoL (183). Yoga has also demonstrated a potential modality in cardiovascular rehabilitation with positive effect in cardiovascular diseases like new highlights on hypertension and atrial fibrillation with promising result showing lower blood pressure, heart rate and improved HRQoL (184, 185).

#### **6.1.6 Yoga and heart failure**

Despite all these positive results from studies of yoga in general, little is known about yoga for persons with HF. Yoga interventions in HF started 2008 with two small RCT studies in a young population with promising results on inflammatory markers and exercise capacity studied by Pullen et.al (186, 187). A small prospective study by Howie-Esquivel looked at 12 persons with HF in NYHA I-II without control group shortly after discharge from hospital. They demonstrated yoga as safe and feasible with improvement in physical function such as strength, balance and endurance but also symptom stability of the dimension of HRQoL (156). Gomes-Neto et al.(188) described in a meta-analysis the effects of yoga among persons with HF. Two studies met the selection criteria with a total of 30 yoga and 29 controls. They stated a significant improvement in peak VO<sub>2</sub> with 22% in favor to yoga and significant improvement in HRQoL with an increase of 24.1%. Even though small studies have shown promising results Cramer et.al (189) gave weak recommendations including two RCT's in their review of yoga for persons with coronary heart disease, HF and cardiac arrhythmias. Findings showed that the mortality and morbidity data was poor, and the studies demonstrated low evidence in exercise capacity and HRQoL. A study by Krishna et al. included 130 persons with HF performing yoga in comparison with CG, showed significant improvements in left ventricular ejection fraction in favor for yoga after 12 weeks. NT-pro BNP was reduced with 64% in the yoga and 11% in CG together with a significant decrease in heart rate, blood pressure and rate pressure product (RPP) in yoga compared to CG (157, 158). Shortly after Kelley et al. carried out a systematic review of previous meta-analyses examining the effects of meditative movement therapies in adults and suggested that meditative movement therapies like yoga, tai chi and qigong may improve HRQOL in adults with selected conditions like HF (190). Metin et.al (191) summarize in their review that mind and body therapies is a safe and cost-effective way to manage HF symptoms and improve



HRQOL. A novelty in yoga is Tele-yoga for persons with HF. This has been evaluated in a small pilot-study and was found acceptable and appropriate (192). However, there has been recent evaluations demonstrating small-to-moderate positive effects on HF outcomes as psychological status, symptom relief, and HRQoL (191, 193). Still, there is a need of gathering information about type of yoga mode, frequency, duration and intensity of the activity in larger multicenter studies (103). Still up to date there is a lack of evidence for guideline recommendations for yoga performance in clinical practice.

## 7 RATIONALE

Between 2000 and 2015 a substantial gain in life expectancy has been shown worldwide (28). Simultaneously there are gaps in the evidence on what can be done to improve the self-care process and HRQoL in persons with HF (16). HF is a very common condition in older persons posing a high burden on the individual affected, due to symptoms of reduced physical capacity, poor HRQoL and decreased mental well-being together with a financial burden on the society, partly due to frequent hospitalization (7, 19, 194). HF is the most common reason to seek care at the emergency department (4). The self-care process is important in persons with HF in order to be able to manage their disease in the best way and reach a stage of stability and better HRQoL (37). Motivation and self-efficacy is of great importance in order to gather information and learn about the disease (195). Together with detecting, monitoring and resolving important factors that can affect the health-status (61). Knowledge of the significance of self-care such as daily weighing, adherence to treatment, detecting early signs of deterioration such as fluid retention, possibilities for medicine adjustment and the positive effects of PA is important for persons with HF (37). The rapid increased use of technology brings an opportunity to support self-care using mHealth (83). Today easy accessible technical tools of mHealth could be of importance for older persons with HF (196). To increase self-care, knowledge and adherence with a possibility to affect hospitalization in HF. In HF PA is a part of self-care and is well established with recommendation in guidelines (4, 114). PA is highlighted as a key component to improve HRQoL (101). Ability to perform increased activity through yoga, as a combination of balance in body and mind, may have effects on HRQoL. To develop and introduce new innovations concerning mHealth and different moods to enhance PA and mental balance in self-care is of great importance for persons with HF. When optimizing self-care in HF, it is also of great value to evaluate and understand experiences of the persons using new technical tools.

## 8 AIMS

The overall aim of this thesis was to describe experiences and evaluate the effects of innovative self-care approaches such as the mHealth system and yoga among persons with heart failure.

### 8.1 SPECIFIC AIMS

**Aim study I** The primary endpoint was to evaluate whether a new mHealth system consisting of a tablet computer connected to a patient scale influenced self-care behavior. Secondary endpoints were health-related quality of life, adherence to mHealth, disease specific knowledge and hospital days due to heart failure after three months.

**Aim study II** To determine the results after six months follow up, using the mHealth system concerning self-care behavior, health-related quality of life, disease-specific knowledge and hospital days due to heart failure, together with an analysis on how the mHealth system was used.

**Aim study III** To test the mHealth system in combination with a theoretical base “the situation specific theory of heart failure self-care” but also to explore the experiences in persons with HF using a tablet computer and develop an understanding of the acceptability, perceived usefulness and potential areas of support.

**Aim study IV** The primary endpoint was to determine whether yoga and hydrotherapy training had an equal effect on disease specific and generic HRQoL. Secondary endpoints were to compare the effects of exercise capacity, clinical outcomes, anxiety and depression between and within the two groups.

## **9 METHODS**

### **9.1 DESIGN**

This thesis is based on four studies combining both quantitative and qualitative methods for data collection and analysis. To immerse knowledge and evaluate the effects of a new mHealth system on HF self-care, HRQoL, disease specific knowledge and hospitalization days, quantitative data was collected. In study I and II a multicenter randomized controlled design was used with a follow-up assessment after three and six months. To get a better understanding of the experiences of the persons who used the mHealth system, a qualitative approach was applied by interviews in study III. Study IV was a single center randomized controlled pilot study with a follow-up assessment after three months comparing two physical interventions, yoga and hydrotherapy by HRQoL, exercise capacity, anxiety/depression and leg-endurance.

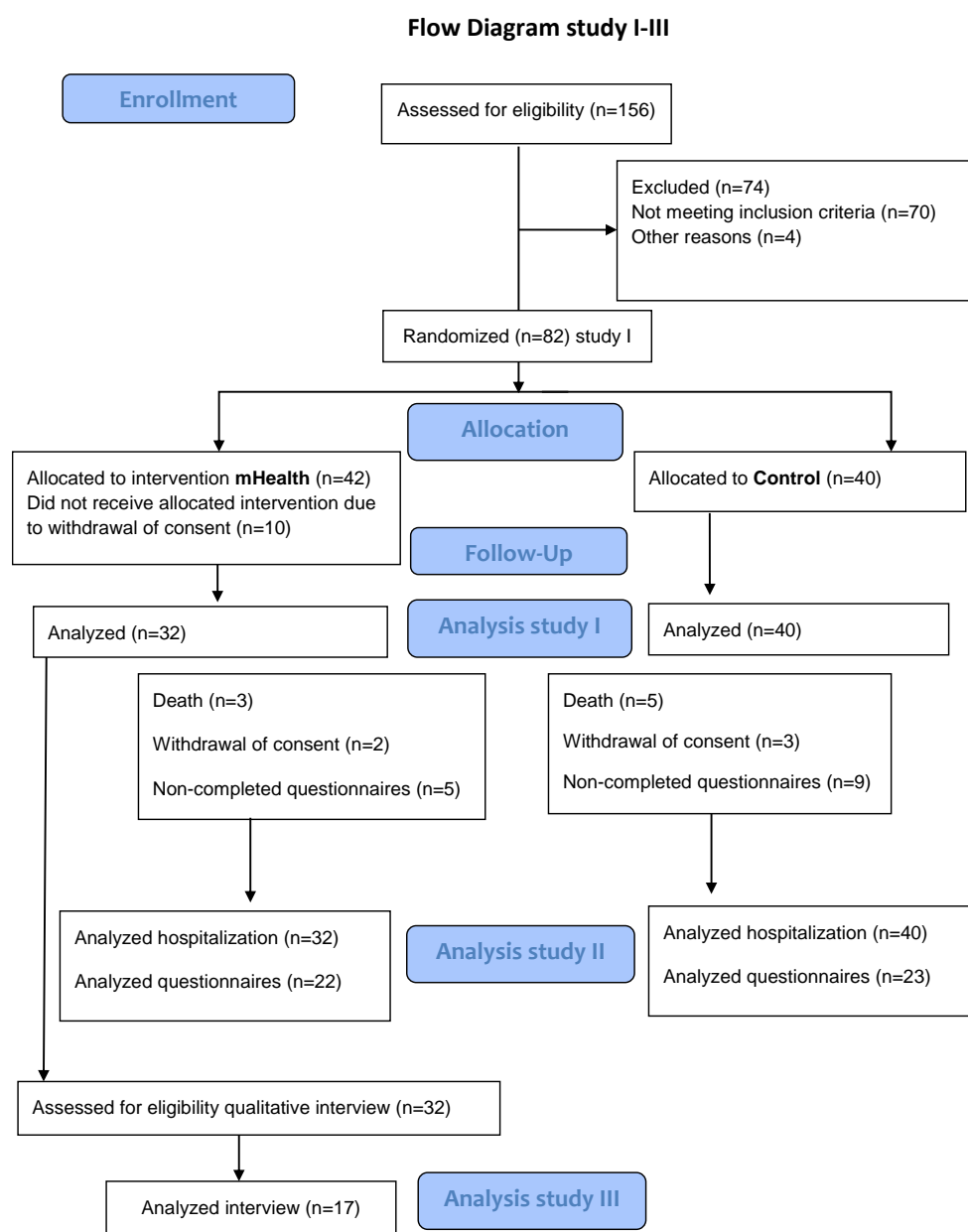
**Table 2.** Overview of design, methods and analyses in study I-IV.

	Study I	Study II	Study III	Study IV
Approach	Quantitative	Quantitative	Qualitative	Quantitative
Design	Randomized controlled multicentered	Randomized controlled multicentered	Descriptive	Randomized controlled single centered
Participants	82 persons with HF	82 persons with HF	17 persons with HF	40 persons with HF
Data collection	Questionnaires	Questionnaires	Semi structured interviews	Questionnaires, physical tests
Data analysis	Descriptive statistics $\chi^2$ test, Student's t-test Mann-Whitney <i>U</i> test Wilcoxon, Poisson-log-linear regression,	Descriptive statistics $\chi^2$ test, Student's t-test Mann-Whitney <i>U</i> test Wilcoxon, Poisson-log-linear regression,	Descriptive statistics Deductive qualitative content analysis	Descriptive statistics $\chi^2$ test, Student's t-test Mann-Whitney <i>U</i> test Paired t-test
Data collected	Baseline and after three months. 22 Febr-18 June 2013	Baseline and after six months. 18 June-10 Nov 2013	During the intervention after three months. April-June2013	Baseline and after three months. Feb. 2011-Jan 2012

HF=Heart failure

### 9.1.1 Study participants

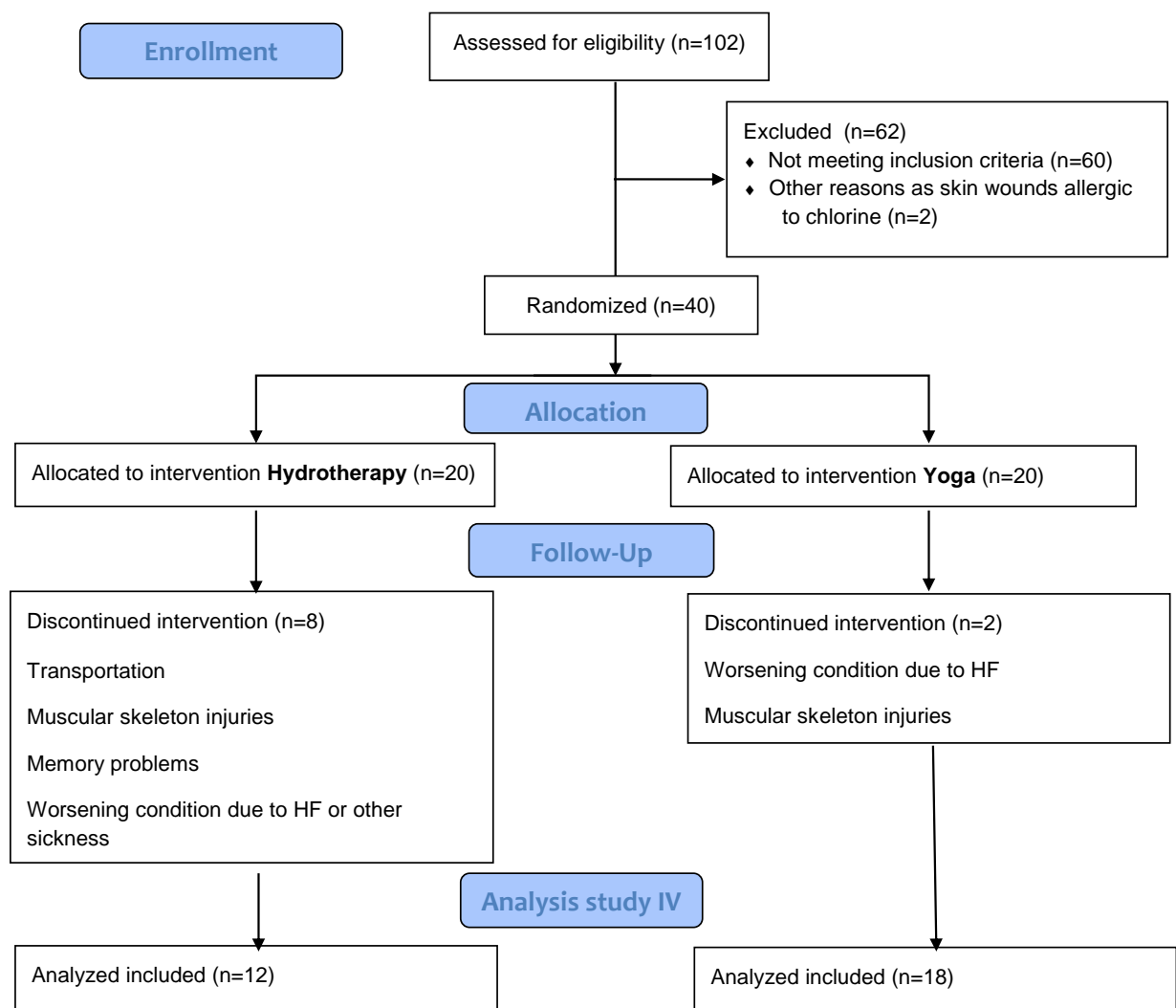
The total number of participants included in all the studies was 211 with 139 unique individuals. Study I-III are based on data from the same individuals, 82 persons with HF that signed the informed consents in three inner city hospitals in Stockholm area, Sweden, Karolinska University hospital, SÖS hospital and Danderyds hospital. In study I-IV the inclusion criteria were HF based on the diagnosis criteria, according to current guidelines of the European Society of Cardiology (144). Forty percent of the persons included in study I and II had a newly diagnosed HF. The persons should not have been referred to a nurse-led HF-clinic within the last year and were referred straight to primary care. All persons were prescribed with diuretics.



**Figure 1.** Flowchart study I-III

Persons randomized in study I and II were referred to either intervention with the mHealth system (n=42) or control (n=40) with usual care, experiencing NYHA class II-IV. Exclusion criteria in study I and II were other serious conditions with a life expectancy less than six month, diagnosed dementia or cognitive impairment of such severity that it would make the person unable to understand provided instructions. Data regarding hospitalization in study I and II were analyzed per protocol based on data from 72 persons who completed the study. An approach of intension to treat analysis was made for the remaining data. Study III was performed as semi-structured interviews from those persons with HF who had used the mHealth system in study I. All (n=32) persons participated in the intervention group with mHealth were asked to participate in an interview and 17 persons approved. The interviews were audio recorded and transcribed verbatim, using a deductive theory-driven approach using “the situation specific theory of heart failure self-care”(43), (Figure 1).

**Flow Diagram study IV**



## **Figure 2.** Flowchart study IV.

In study IV the persons were randomized to exercise two times per week by either hydrotherapy (n=40) or yoga (n=40). The inclusion criteria were HF in NYHA-class I-III and all had visited the out-patient HF clinic for optimizing of the medical treatment prior to enrolment. Persons with diagnosed dementia, other serious conditions with a life expectancy of less than six months or scheduled for heart transplantation were excluded. Furthermore, those unable to understand oral instructions were excluded. An upper age of 80 years was chosen in study IV. Persons addicted to alcohol or drugs, incontinent, having wounds or being allergic to chlorine were also excluded, (Figure 2).

### **9.1.2 Sample size**

Weighing in study I and II was a fundamental part of the intervention with the mHealth system. A choice of the frequency of weighing found in the literature at the current time looking for the effect size of a similar intervention (197). An estimated adherence of 30% in CG and 80% in IG resulted in 30+30 persons required to reject the null hypothesis with 80% power and a type I error probability of 5%. Considering the potential loss of persons, there was a target enrollment by 40 persons in the CG and 40 persons in the IG. The power calculation was performed by “Know It Decision” by a consulting agency on Dec 2012 (145). Study IV was a pilot study and therefore was no sample size estimated.

## **9.2 PROCEDURES AND INTERVENTIONS**

### **9.2.1 The mHealth system**

Optilogg® can be described briefly as a compliance catalyst m-Health system developed in cooperation with hospital staff and evaluated in study I-III. It consisted of a tablet computer locked to a custom software prepared in advance and wirelessly connected to a weight scale installed in the person’s home. In stepping on the weight scale every morning, the weight was transferred to the tablet. Based on the weigh a built-in intelligence could detect a deterioration in the HF status and titrate the dose of diuretics. The tablet gave self-care advices and flexible doses of diuretic in case of deterioration with a weight increase > 2 kg in 3 days. The tablet was divided into four different selectable areas. The first was an automatic view that started every day when the person stepped on the scale with the weight in kilos, together with the recommended dosage of diuretics and a short tip on lifestyle recommendation HF self-care maintenance (37, 198). The second was a selectable view of content information of the HF disease (144) and lifestyle self-care recommendations according to current guidelines (37, 199) for example like physical activity, smoking cessation, healthy salt-restricted food, fluid



restriction and immunization. The third area of choice was a view containing a graphical image of trends showing variations in weight, use of diuretics and well-being over time with a Visual Analogue Scale (VAS) of HRQoL, including zoom and scroll functions. The last optional area, contained contact details to responsible nurses and doctors at the outpatient HF clinic and to persons responsible for technical support. Every fifth day the persons estimated their HRQoL on the VAS scale that was stored in the third section. The m-Health system gave possibility to search for information in the tablet like adaptive education with a visual feedback trend at any time concerning self-care maintenance as performance of weight results, self-care management as diuretic medicine consumptions and generic HRQoL by the VAS. When the m-Health system detected HF deterioration instructions were given to up-titrate the diuretics. If no change was noted after three days, instructions were given to contact the healthcare provider. To assist in case of technical problems all had access to technical support. No data was sent to the hospital, which was an integral part of the mHealth system design.

### **9.2.2 Hydro-therapy**

The persons randomized to hydrotherapy in study IV were on optimal medical treatment and had received self-care advice according to current guidelines by an out-patient HF clinic at the hospital (37, 144). A 45-minute hydrotherapy session was conducted twice a week in a heated therapy pool at the hospital. The water temperature was 31-32 degrees Celsius. The persons standing could reach the bottom of the pool. Each session consisted of endurance training in water in a standing, sitting or lying position. Training a single muscle group at a time, the exercises involved the arms, shoulders, back, stomach, seat and leg muscles. The exercise regime was designed to include muscles utilized in daily living such as walking, dressing and household activities. The focus was to exercise one muscle group at a time with the water as a resistance. The hydrotherapy followed a low to medium exercise level, with the central exercise level of 11-13 Borg RPE-20 scale and with 2x15 repetitions/muscle group (124, 125, 127). The hydrotherapy sessions were conducted by a certified physical therapist. The persons training hydrotherapy were asked to complement with a daily exercise program consisting of easy movements using the persons own weight together with a daily walk.

### **9.2.3 Yoga**

The yoga performed in study IV springs originally from Kundalini yoga and is named Mediyoga® (200). The postures used in Mediyoga® are generally slower and more gently than in traditional yoga of Kundalini (see Appendix A). The yoga postures consisted of a combination of forward, backward and sideward bends, twists and balance poses individually

modified according to medical or orthopedic limitations if needed. The persons had received optimal medical treatment and self-care advices according to current guidelines through an out-patient HF clinic at the hospital (37, 144). In addition to the usual HF treatment, the persons randomized to yoga performance, received a 60-minute yoga class twice a week. The yoga postures were performed standing, seated on chairs or yoga mats or lying down. Each person performed a total of 20-24 sessions over a three months period. Every second week the sessions and meditations alternated between two different sets of combinations of yoga exercises specially design to enhance the heart. A session included 10 minutes deep breathing exercises, 40 minutes of yoga postures and finally 10 minutes of relaxation together with meditation. At the end of each session, participants had the opportunity to discuss their experiences or issues. At the first visit everybody received a CD and a hand-out with yoga postures together with written instructions. The yoga sessions were performed at the hospital and conducted by a certified yoga instructor. The persons were encouraged to practice yoga at home with a goal of one session a day.

#### **9.2.4 Control conditions**

In study I, II the persons randomized to control group received the same basic HF information sheets as those randomized to intervention. The information sheet consisted of advices regarding HF self-care according to current guidelines with suggested action of increased dose of diuretics in case of weight gain (37, 198) and with a priority number to call in case of need.

### **9.3 DATA COLLECTION AND MEASUREMENTS**

Background variables and participants characteristics such as age, gender, marital status, comorbidity, new onset of HF, NYHA classification and medication was collected through medical files and interviews. Study I- III were multicentered studies with three hospitals in Stockholm, Sweden. Study IV was a single centered study. Data in studies I, II and IV were systematically collected using questionnaires. The questionnaires were completed at inclusion and at three months follow up in hospital I and IV. In study II six months follow-up was made by sending the questionnaires in a stamped envelope in return to the hospital. In study I and IV blood samples were collected at the hospital or at a local laboratory. The capacity tests 6MWT and STST test in study IV were performed at the hospital mostly with help from the local physiotherapist. In study II information about death and cause of death during the follow-up were collected from medical records. In study III data were collected through semi structured interviews using an interview guide at the hospital or at the persons home (Figure 3).

### **9.3.1 Hospitalization**

The number of hospital days due to HF were collected at baseline and after 90 and 180 days in study I and II. We made a compilation of the HF-related hospital days during the same period using information collected from the medical records.

### 9.3.2 Instruments

**Table 3.** Variables and instruments used in study I, II and IV.

Study	Variables tested	Instruments	*	**	***
IV	Exercise capacity	<b>6MWT</b> – Six-minute walk test			
I,II,IV	HRQoL	<b>KCCQ</b> - The Kansas City Cardiomyopathy Questionnaire	☒		☒
I,II	HRQoL	<b>SF-36</b> -Swedish version of the Health Survey		☒	☒
IV	HRQoL	<b>EQ-5D</b> - EuroQol-5D		☒	☒
I,II	Heart failure Self-care	<b>EHFScB9</b> scale -The European Heart Failure Self-care Behavior Scale	☒		☒
I,II	HF knowledge	<b>DHFKS</b> - Dutch Heart Failure Knowledge Scale	☒		☒
IV	Anxiety and Depression	<b>HADS</b> - Hospital Anxiety and Depression Scale	☒		☒
IV	Depression	<b>PHQ9</b> - The Patient Health Questionnaire depression module	☒		☒
IV	Leg endurance test	<b>STS test</b> - Functional in the lower limb muscle measured by the sit-to-stand test			
I,II	Readmission hospital days	Medical records			

\* Disease specific instruments, \*\* Generic instruments, \*\*\*Tested in the Swedish population

#### *Six-minute walk test*

The 6MWT reproduces the activity of daily life and this is particularly relevant in elderly persons who usually develop symptoms below their theoretical maximal exercise capacity. The 6MWT is a standardized, reproducible, low-tech test of exercise capacity that measures the distance a person can walk on a flat, hard surface in six minutes. It evaluates the global and integrated responses of all the systems involved during exercise. Evaluation includes the pulmonary, cardiovascular, systemic and peripheral circulation. Age, height, weight and gender, independently affect 6MWT (114, 201-204). The distance of relevance in HF is estimated to be between 30-36 m of change (205, 206). Borg's Rating Perceived Physical Effort scale (207) was measured before and after 6MWT together with blood pressure, pulse rate and peripheral oxygen saturation test using an equipment from Nellore Oxi Max N-65P. The 6MWT was used in study IV at baseline and after three months (Table 3).

### ***Sit-to stand test***

The lower limb muscle function is measured by a sit-to-stand test. The test required the person to stand up from and sit down on a slightly padded 43 cm high armless chair as quickly as possible for 30s. Persons were instructed to fold their arms across their chest and stand-up completely and make firm contact when sitting. On the command of “go” the timing started and ceased when the person sat after 30 s and the amount of performed movements were counted and used in the subsequent analysis. Persons could practice two repetitions. The test has been performed in older populations but the validation in the HF population is discussed (208-211). The STS test was used in study IV at baseline and after three months (Table 3).

### **The Kansas City Cardiomyopathy Questionnaire**

KCCQ is a disease-specific instrument measuring HRQoL with 23-items, that quantifies six domains and two summary scores of a person’s health status. The six domains are physical limitations, total symptom score, symptom change, self-efficacy, social interference and quality of life. The two summary scores are clinical summary scores and overall summary scores. The items in KCCQ have five to seven response alternatives. All scale scores are transformed to 0-100 scale, with a higher score indicating better HRQoL. The instrument has been tested and validated in a Swedish HF population (36, 212). The KCCQ instrument was used in study I and II at baseline and after three and six months and in study IV at baseline and after three months (Table 3).

### ***Swedish version of the Health Survey Short Form 36***

SF-36 is a frequently used instrument to assess generic HRQoL both physically and mentally. The instrument includes eight multi-item scales plus a single-item scale, to compare the persons current health with the health one year ago. The eight domains are physical functioning, physical role, bodily pain, general health vitality, social functioning, role of emotional health and role of mental health. SF-36 also consists of two summary scores; mental component score (MCS) and physical component score (PCS). The scores are transformed into a scale where higher scores indicate better HRQoL ranging from 0-100 with 0 as worst possible health and 100 as best possible health. The SF-36 has good reliability and validity and is tested in the Swedish population (32, 213, 214). The SF-36 instrument was used in study I and II at baseline and after three and six months (Table 3).

### ***EuroQol-5D***

EQ5D is a generic instrument and measures health related quality of life. The EQ-5D consists of two parts. The first part includes 5 dimensions of health state classification (mobility, self-care, daily activities, pain/discomfort, anxiety/depression). The responses are classified in 3

levels of severity (1 = no problems, 2 = moderate problems and, 3 = severe problems). The answers in each of the scales are graded and given an index according to a weight transformed to 1.0 representing full health and -0.59 representing the lowest possible health index. The index score (EQ-index) can calculate 243 theoretical possible health statuses. The second part of EQ-5D is the Visual Analogue Scale (EQ-VAS) that evaluates self-rated health on a vertical, visual analogue scale, where the endpoints are labeled 0 (worst imaginable health state) to 100 (best imaginable health state). EQ5D has good feasibility, validity and reliability (33, 215-217). This instrument was used in study IV at baseline and after three months (Table 3).

#### ***The European Heart Failure Self-care Behavior Scale***

EHFScB-9 is an instrument that measures self-care behavior that persons with HF perform to maintain life, wellbeing and healthy functioning. The EHFScB-9 scale consists of nine-items with alternative answers on a five-point Likert scale from 1 (I strongly agree) to 5 (I strongly disagree). The total score ranges between 9-45 and lower scores indicates better self-care behavior. The reliability of this score is tested with Cronbach's alpha method with consistency usually between 0.68 and 0.87 in different countries. The EHFScB-9 scale has been tested and found to be user friendly and have good reliability and validity (197, 218, 219). This instrument was used in study I and II at baseline and after three and six months (Table 3).

#### ***Dutch Heart Failure Knowledge Scale***

DHFKS has 15 questions concerning knowledge about HF. Each question has 3 fixed alternative answers. The correct answer gives 1 point (range 0-15). The instrument has been tested and found to be user friendly and have good reliability and validity (220). The DHFKS was used in study I and II (Table 3).

#### ***The Hospital Anxiety and Depression Scale***

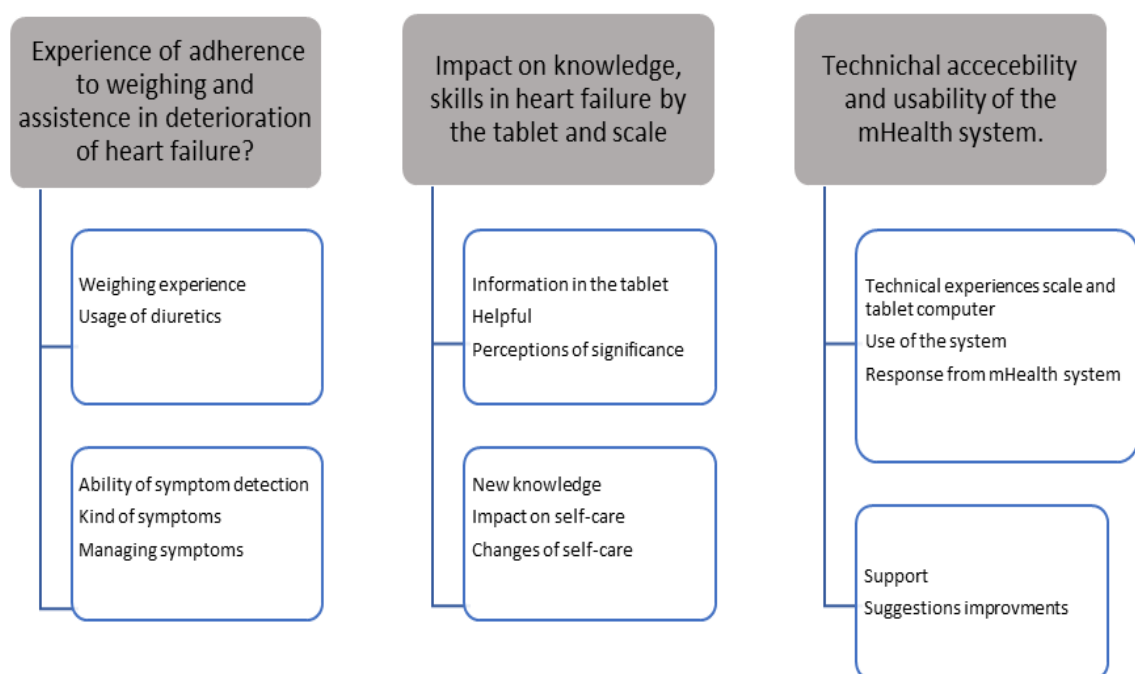
HADS is a valid and reliable instrument used in HF. The scale consists of 14 statements that are answered on a four-point scale. Seven statements designed to measure anxiety (HADS-A range 0-21) and seven measures depression (HADS-D range 0-21). This test can validate the existence of symptoms together with their severity. (221, 222). The HADS was used in study IV at baseline and after three months (Table 3).

#### ***The Patient Health Questionnaire depression module***

PHQ-9 is a brief self-rating scale for screening major depressive disorder and measuring the current level of symptoms of depression. Each of the nine-items are scored from 0 to 3, with 0 meaning no symptoms at all and 3 symptoms nearly every day. The sum of the scores can

be used as a measure of current symptom level to assess depression depth and follow a progression over time. PHQ-9 scores of 5, 10, 15, and 20 represented mild, moderate, moderately severe, and severe depression, respectively. The instrument is a reliable and valid measure of depression severity (223). PHQ9 was used in study IV at baseline and after three months (Table 3).

The main research question of interest in study III was to develop an understanding of the experiences from persons with HF using the mHealth system, a tablet computer wirelessly connected to a weight scale. The first question in the interview was concerning the main aspects of phenomena that were investigated: “Can you tell me about your own experiences of using the mHealth system?” To get a deeper understanding of the experiences, follow up questions was used like: Direct questioning of what just had been said or mere nod, or “mm” or a pause. Mostly probing questions was used like: “Can you tell me in what way you found..?” or “Please tell me how you experienced...?” “Can you please elucidate me more about...?” Structured questions were used to indicate when an area had been exhausted, to move to the next topic. In the interview there was allowance of reflected silence with active listening. Interpreting questioning to clarify and rephrasing was used. With attention to the linguistic nature of the interaction in the interview, there was a focus on the wording of the questioning, which was adapted to the subject matter and the purpose of the study (Figure 3).



**Figure 3.** Interview topic guide with semi structured directed areas.

## 9.4 DATA ANALYSIS

### 9.4.1 Statistical analysis

In study I, II and IV basic statistics were used consisting of descriptive statistics, correlations, t-test and various tables to organize and describe the study variables and populations. Depending on the examined variable different methods of parametric or non-parametric tests were chosen. As a measure of position, the data was tested for normality. The results were presented as mean, median or quartiles for numerical data. Categorical variables were presented as frequencies and percentages. In measuring the dispersion, the variance, standard deviation, interquartile range or range was used. The data was presented as graphs and/or tables as appropriate. Univariate statistics on differences of baseline variables were calculated by the Student t-test if normally distributed or if not by Mann-Whitney test. Descriptive statistics were expressed as means  $\pm$  standard deviation (SD) for continuous variables. For categorical variables medians with interquartile range (IQR) and/or frequencies and percentages was used. Differences in means, medians or ratio were tested by 1-way analysis of variance, Kruskal-Wallis test or multifrequency cross-tables. If both variables tested were numeric the Pearson's parametric or Spearman's non-parametric correlation was performed depending on normality and variance. If one variable was numeric and the other variable categorical with normality and equal variance a t-test for independent samples was used to discover differences between the groups. If data was not normally distributed or without equal variance, differences were tested by Mann-Whitney test.

In study I and II correlation between two independent categorical variables were tested with chi-square statistics. In post-hoc analyses, Student t-test, Mann-Whitney U test or x-test were used as appropriate. In study II differences between the intervention and control were analyzed using a  $\chi^2$  test or a Student's t-test for independent samples. Log-rank test was used for time to death or heart failure hospitalization, for survey-based variables. To analyze the number of hospital days per person and six months a Poisson log-linear regression was performed. Other outcome variables consisting of one categorical and one numerical the Mann-Whitney for independent and for dependent samples the Wilcoxon test were used.

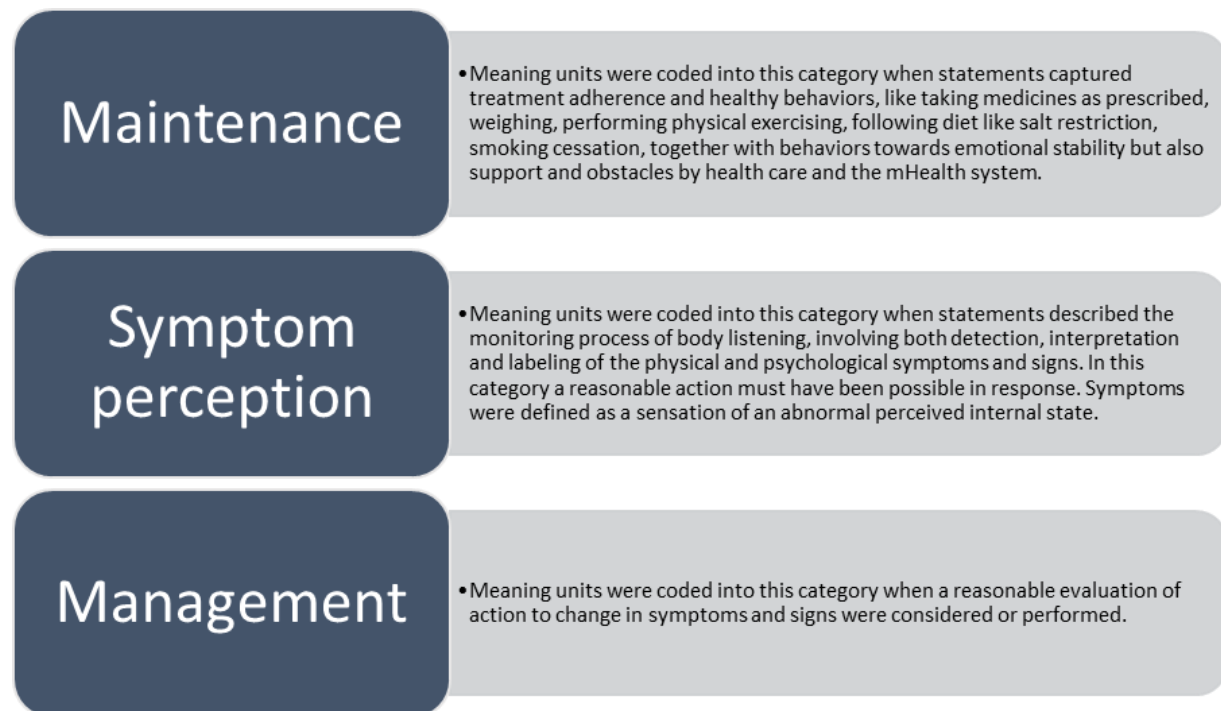
In Study IV the descriptive statistics were expressed as means and standard deviations for numeric variables. Categorical variables were presented as frequencies. Univariate statistics on differences of baseline variables were calculated by the  $\chi^2$  test, Mann-Whitney test or Student's t-test depending on numeric or categorical variables. Differences between the persons performing hydrotherapy and yoga were analyzed using a Student's t-test for independent samples. Within group analysis were performed using paired t-test.

Statistical calculations in study I, II were performed in R, version 3.0.1. and in study IV



PASW statistics version 18 (IBM Corporation 2010, IBM Corporation, Route 100 Somer, NY 10589). The level of statistical significance was  $p < 0.05$  for study I, II and IV.

### 9.4.2 Qualitative analysis



**Figure 4.** Coding framework of the predetermined categories, based on “the situation specific theory of heart failure self-care”.

A qualitative design was used in study III with semi structured interviews following an interview guide, (Figure 3) and analyzed by inspiration of qualitative manifest content analysis (224). Using a deductive approach relating to “the situation specific theory of heart failure self-care” (43), (Figure 4). The deductive analysis process started with three main phases: preparation, organizing and reporting in a manifest content way. Meaning units were elected from the data followed by a coding according to a structured matrix consisted of the tree categories within the theory of self-care. The data summaries into codes and further into sub-categories which was the base for presentation (Table 4).

**Table 4.** Meaning units (MU), codes and sub-categories in study III. Unpublished data

CATEGORY	MU	CODES	SUB-CATEGORIES
Maintenance MU=181	39	Weight	<i>Adherence</i> MU=82
	18	Routines	
	11	Diet	
	8	Fluid restriction	
	6	Physical activity	
	29	Health care	<i>Support</i> MU=67
	24	Self -care advice	
	14	Medical treatment	
	32	Heath care	<i>Obstacles</i> MU=32
	36	Weight gain	<i>Physical symptoms</i> MU=61
Symptom perception MU=67	8	Fluid retention	
	6	Swollen legs	
	3	Coughing	
	3	Obesity	
	2	Physical impairment	
	4	Dyspnea	
	3	Non-well being	<i>Psychological sensations</i> MU=6
	2	Fatigue	
	1	Stress	
	11	Insight in HF treatment	<i>Developing and using skills</i> MU=41
Management MU=63	9	Evaluation of treatment	
	8	Decision making	
	5	Healthy lifestyle	
	5	Keeping fluid restriction	
	3	Keeping diet	
	14	Self-care medical treatment diuretics	<i>Independence</i> MU=20
	2	Not following fluid restriction	
	1	Not taking diuretics	
	1	Not following smoking restriction	
	2	Call health care professionals	<i>Cooperation</i> MU=2

## **ETHICAL CONSIDERATIONS**

The goal was to perform all studies per principles of autonomy, not harming, beneficence, with justice and respect for human rights described in the World medical association Declaration of Helsinki (225). To do so there was primarily permission obtained from the Regional Ethical Review board in Stockholm for all studies, study I (DNR: 2012/2176-31/1) study II (DNR: 2012/2176-31/1) study III (DNR: 2013/1778-32) and study IV (DNR: 2010/1452-31/4). All persons received verbal and written information about the studies before signing a written consent before entering the studies. A patient is always in an inferior position and dependent on health care, especially when newly diagnosed and not in the best of health. To ask for participating in a study may augment the dependent position of the person. This could be avoided as in study I, II and III with the researcher not involved in the clinical care of the persons participating. The numbers of questionnaires were carefully considered prior to the studies, the time and effort given by the persons participating, filling in all the data in questionnaires and discomfort of pain caused by blood samples and exhaustions due to physical tests were considered. Respect was paid to the persons privacy and serious condition. Participation in the interventions in study I, II and IV may have resulted in large commitments, as dedicated time to perform the interventions and costs for traveling. In return the participants were examined and followed-up for their HF at the hospital free of charge. In study IV they could keep the received free yoga material after the intervention. The persons in study I and II could not keep the technical mHealth tool that they had used. All the persons participating in interventions with an instructor in hydrotherapy or yoga in study IV was free of charge. In cases where the persons were expected to send questionnaires to the research team, they were provided with pre-stamped envelopes. Study III that was an interview study to evaluate experiences of the mHealth tool used for three months. The persons may have participated in the interviews as obligations and as a sign of gratitude and may not have revealed negative experiences.

## 10 RESULTS

A total of 82 persons accepted to participate in study I and II and completed the baseline measures, but the results are based on the results of 72 persons that completed the study. In study III 32 persons were asked to take part in an interview and 17 persons agreed. In study IV 40 persons accepted to participate and the results are based on the 30 persons that completed the three months follow-up. Demographic data shown in Table 5.

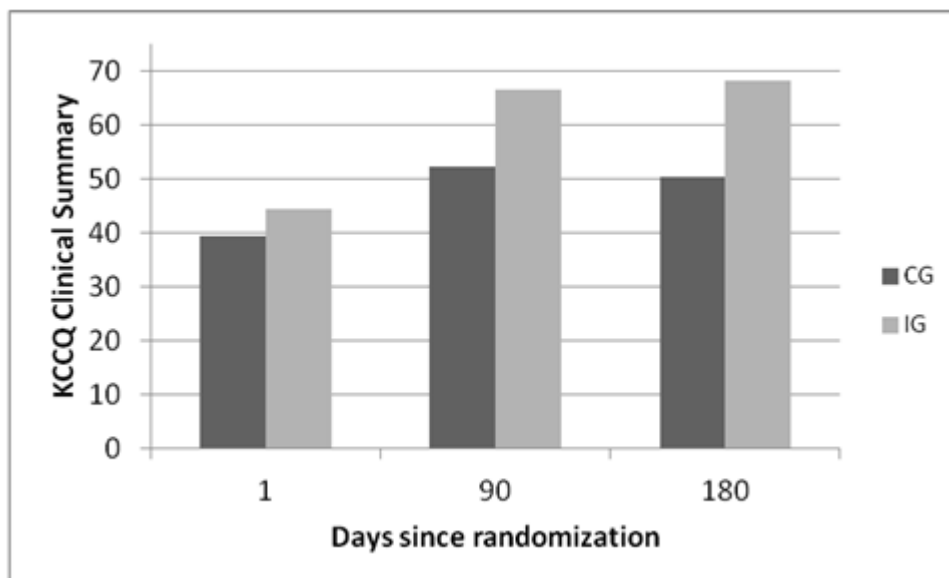
**Table 5.** Demographic and clinical characteristics, comorbidity and medication for participants in study I-IV.

Variable	Study I		Study II		Study III	Study IV	
	IG (n=32)	CG (n=40)	IG (n=32)	CG (n=40)	n=17	YG (n=18)	HG (n=12)
Gender % female	66	70	66	70	35	25	45
Age, mean (SD±), y	75(8)	76(7)	75(8)	76(7)	75(8)	64.1(9.4)	65.7(8.5)
Civil status, single %					23		
<b>Drugs</b>							
ACE-I %						90	90
ACE-I/ARB %	69	78	69	78			
Betablockers %	97	88	97	88			
Diuretics %						75	95
Furosemide equivalent %	100	100					
Loop diuretics dose/mg	65(65)	92(66)					
Statins %						35	50
Warfarin %						35	45
MRA %	38	30	31	30		25	35
<b>Co-morbidities</b>							
Myocardial infarction %	22	23	22	23		35	40
Ischemic heart disease %			9	18		20	20
Atrial fibrillation %	47	73	47	73		40	40
Diabetes mellitus %	34	45	34	45		15	15
Stroke %						5	5
Hypertension %	56	45	56	45		30	20
COPD %	13	23	13	23		0	0
Cancer %						1	1
Hyperlipidemia %	6	8	6	8			
Renal failure %	9	8	9	8			
Syncope %	6	3	6	3			

Newly diagnosed %	47	35	47	35	41	
<b>Lab tests</b>						
Creatinine (SD)	112(37)	107(98)			82.3 (19.5)	110.2 (47.2)
Hemoglobin (SD)					136.5 (17.4)	134.0 (14.5)
NT-ProBNP (SD)					1408 (1419)	1589 (1703)
<b>Devices</b>						
Pacemaker %					10	10
CRT %					10	20
ICD %					15	35
CRT-P/CRT-D/ICD %	16	20				
<b>NYHA</b>						
I %					25	35
II %	38	18	38	18	40	30
III %	62	82	63	83	35	35

Continues variables are presented as mean (SD±) and categorical variables are presented as percentages.  
 CRT:cardiac resynchronization therapy; ICD:implantable cardioverter defibrillator; NYHA:New York Heart Association Classification; COPD:Chronic obstructive pulmonary disease; MRA:Mineralocorticoid receptor antagonist; ACE-I:Angiotensin-converting enzyme inhibitors; ARB:Angiotensin II-receptor antagonist.

### 10.1.1 Health related quality of life and depression/anxiety



**Figure 5.** Results of the instrument KCCQ in study I, II measuring disease specific knowledge at baseline, three months and six months. Results from three months reprinted from Sc.Card.J with permission from Taylor & Francis. Results from six months are unpublished data.

The disease specific HRQoL measured by KCCQ improved with significantly higher score at three-month follow-up in study I (median IG 65.1 [IQR: 38.5, 83.3]) vs. CG (median 52.1 [IQR:41.1, 64.1] p=0.05). Physical limitation improved (median IG (54.2 [IQR: 37.7, 83.3]) vs. CG (45.8 [IQR: 25.0, 54.2] p=0.05). After six months there was further improvement in disease specific HRQoL with median IG (72.7 [IQR: 50.8, 87.9]) vs. median CG (51.8 [IQR: 40.9, 62.8] p=0.05) in study II (Figure 5). HRQoL measured by the generic instrument SF-36 was not different between the two groups regarding mental or physical score at baseline three or six months follow-ups in study I and II.

**Table 6.** Comparisons between and within the yoga and hydrotherapy interventions of effects on health-related quality of life and symptoms of depression at baseline and after 12 weeks follow-up.

	Yoga baseline (n=20)	Hydro- therapy baseline (n=20)	Yoga follow up (n=18)	Hydro- therapy follow up (n=12)	Between groups baseline P-value	Between groups follow up P-value	Within groups yoga P-value	Within groups hydrotherapy P-value
EQ-5D	0.67±0.26	0.76 ±0.28	0.72±0.26	0.84±0.14	0.34	0.11	0.85	0.39
EQ VAS	63.7±19.2	71.3±19.5	77±13	71±26	0.22	0.50	<b>0.004</b>	0.64
KCCQ Physical Limitation	67.1±22.5	70.1±23.4	73.8±23.9	77.4±19.0	0.60	0.65	0.17	0.09
KCCQ Symptom Stability	53.8±16.8	57.5±16.4	51.4±20.1	56.3±18.8	0.48	0.51	0.67	0.50
KCCQ Symptom Frequency	71.8±27.3	81.0±21.0	81.9±21.1	84.4±12.4	0.23	0.70	<b>0.03</b>	0.50
KCCQ Symptom Burden	72.1±26.0	80.8±20.8	79.2±22.6	84.0±17.2	0.25	0.51	0.29	0.54
KCCQ Total Symptom	72.0±26.0	80.9±19.2	80.6±21.0	84.2±14.0	0.22	0.57	0.08	0.48
KCCQ Self-Efficacy	58.1±24.4	71.3±22.6	67.4±22.3	76.0±17.2	0.09	0.24	<b>0.01</b>	0.17
KCCQ Quality of Life	61.7±28.1	65.8±26.6	73.1±19.5	72.2±18.9	0.63	0.90	0.09	0.21
KCCQ Social Limitation	60.6±26.6	68.1±28.6	68.1±23.4	77.6±21.2	0.40	0.26	0.21	0.20
KCCQ Clinical Summary	69.5±22.8	75.9±19.2	77.2±21.8	80.8±14.8	0.35	0.59	<b>0.05</b>	0.17
KCCQ Overall Summary	65.3±22.5	71.4±20.5	73.9±18.1	77.9±16.1	0.38	0.54	<b>0.04</b>	0.12
PHQ-9	7.6±5.6	4.1±4.4	4.22±3.3	3.0±1.7	<b>0.03</b>	0.20	<b>0.005</b>	0.23
HADS-depression	3.1±3.1	3.9±5.5	2.0±2.2	1.9±1.9	0.55	0.91	0.25	0.17
HADS-anxiety	4.6±4.1	4.6±4.3	2.7±3.2	3.9±3.4	1.0	0.34	<b>0.01</b>	<b>0.03</b>

EQ-5D index = EuroQol five dimensions summarized index, EQ VAS=EuroQol visual analogue scale, KCCQ=Kansas City Cardiomyopathy Questionnaire, PHQ= Patient health Questionnaire, HADS=Hospital Anxiety and Depression Scale. Reprinted from the Eur.J of Card Nurs with permission from SAGE.

No significant differences were found between groups in patient-reported or clinical outcomes at baseline in study IV. Yoga and hydrotherapy had equal impact between groups on disease-specific and generic HRQoL, anxiety and symptoms of depression after three months,

anxiety decreased (hydrotherapy  $P=0.03$  and yoga  $P=0.01$ ). Persons in the yoga group significantly improved their generic HRQoL measured by EQ-VAS ( $P=0.004$ ) and their disease-specific HRQoL in the following domains of KCCQ; symptom frequency ( $P=0.03$ ), self-efficacy ( $P=0.01$ ), clinical summary score as a combined measure of symptoms and social factors ( $P=0.05$ ), and the total overall summary score for the whole instrument ( $P=0.04$ ) and decreased their symptoms of depression according to PHQ-9 ( $P=0.005$ ) (Table 6).

### **10.1.2 Physical and clinical measurements**

In study IV no significant differences were found between the groups in any of the clinical or person-reported outcomes at baseline. Between groups there was no significant differences after three months. Within group comparisons showed improved exercise capacity (hydrotherapy  $p=0.02$  and yoga  $p=0.008$ ) in both groups after three months. In study IV hydrotherapy training showed a significant improvement in lower limb muscle strength by STS test ( $p=0.01$ ) (Table 7).



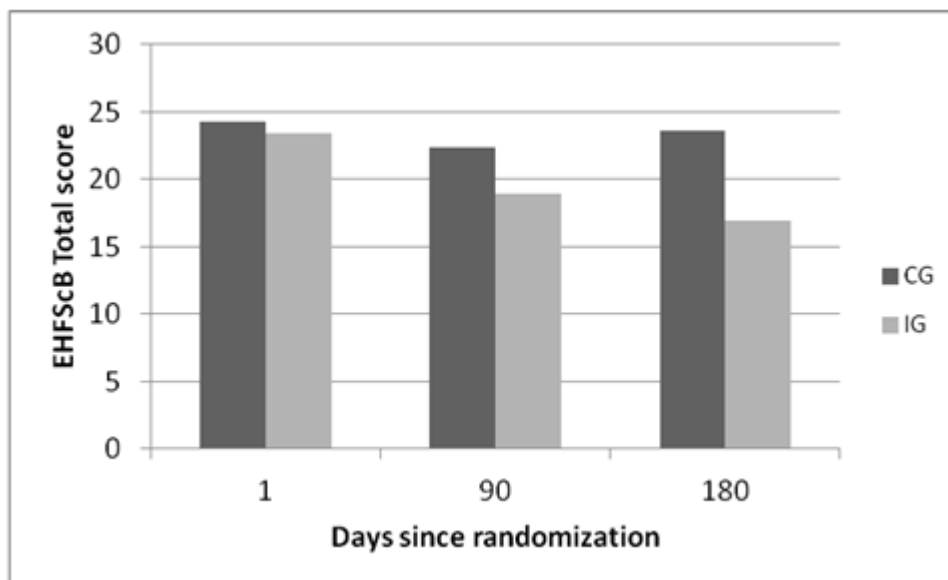
**Table 7.** Comparisons between and within the yoga and hydrotherapy interventions regarding exercise capacity, lower limb muscle strength and clinical variables at baseline and after 12 weeks follow-up.

	Yoga baseline (n=20)	Hydro- therapy baseline (n=20)	Yoga follow up (n=18)	Hydro- therapy follow up (n=12)	Between groups baseline P-value	Between groups follow up P-value	Within groups yoga P-value	Within groups hydrotherapy P-value
6-minute walk test	453.6±126.7	455.8±103.9	486±133	488±110	0.95	0.98	<b>0.008</b>	<b>0.02</b>
Sit-to stand test	31.7±14.6	26.8±11.7	25.8±13.2	21.1±8.2	0.25	0.25	0.09	<b>0.01</b>
Systolic BP mmHg	119.8±19.2	124.8±21.9	122±17	124±22	0.45	0.76	0.86	0.77
Diastolic BP mmHg	71.3±12.1	77.1±10.6	77±11	80±10	0.12	0.25	0.26	0.60
Pulse beats/minute	63.7±9.0	74.8±14.4	70±15	79±21	0.07	0.21	0.29	0.57
Saturation %	98±1.6	97±1.8	98±2	97±2	0.56	0.38	0.13	0.85
Sensitive CRP mg/L	2.6±2.6	3.7±6.8	2.0±1.4	4.6±5.1	0.61	0.20	0.14	0.18
NT proBNP ng/L	1408±1419	1589±1703	1523±1366	1794±1200	0.71	0.59	0.90	0.69

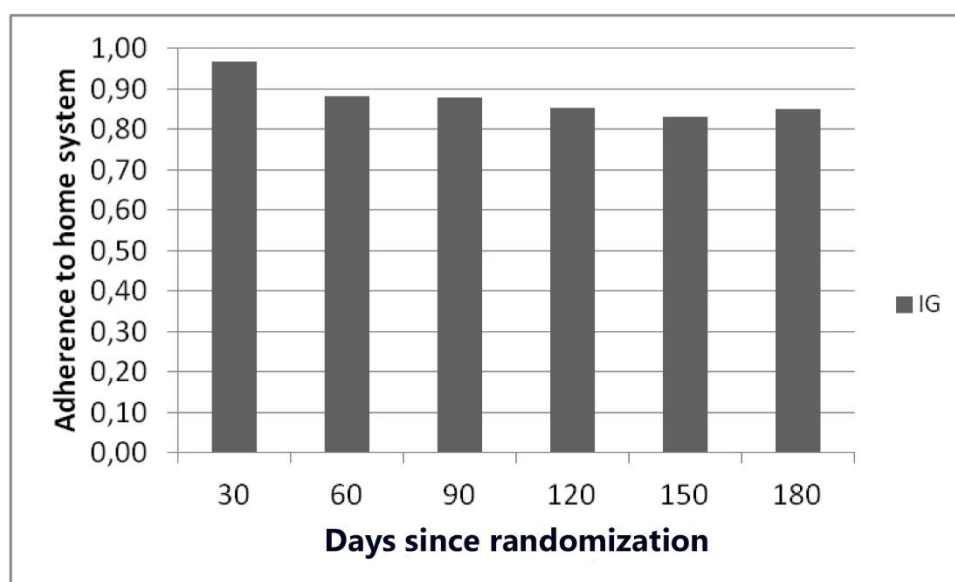
BP= blood pressure, hsCRP= High Sensitive C-reactive protein, NT proBNP = N-terminal prohormone of brain natriuretic peptide. Reprinted from the Eur J of Card Nursing with permission from SAGE

### 10.1.3 Self-care behavior and adherence

The two groups IG and CG were balanced at randomization at baseline in both study I and II. Self-care behavior measured with EHFS<sub>CB</sub>-9 after three months displayed an improvement in the IG median (17 [IQR: 13, 22]) in comparison with the CG median (21 [IQR: 17, 25]) (p<0.05) in study I. The same indication with lower results in EHFS<sub>CB</sub>-9 indicating a better self-care behavior was also measured at the six months follow-up in study II median IG (16.5 [IQR:12, 22]) vs. median CG (23.5 [IQR 18.8, 30,0] p=0,05) (Figure 6).



**Figure 6.** Results of the instrument EHFSdB-9 measuring self-care behavior at baseline, three months and six months. Results from three months reprinted from Sc.Card.J with permission from Taylor & Francis. Results from six months are unpublished data.



**Figure 7.** Adherence to the mHealth system during six months. Results from three months reprinted from Sc.Card.J with permission from Taylor & Francis. Results from six months are unpublished data.

In study I II adherence to the mHealth system was high with a median of 85-88%. A post-hoc analysis was performed with a 60%-point adherence as cut off to test effects on cardiac hospitalization. For the subgroup of IG who displayed an adherence to the system  $> 60\%$  there was a reduction of 5.6 hospital days per person. A statistical correlation was used for the fact that the group diminished further in size and the results were significant ( $p=0.05$ ) (Figure 7). In study III adherence to mHealth was expressed as important and strengthened weighing performance.

#### **10.1.4 Disease specific knowledge**

There was no difference in disease specific knowledge measured with the instrument DHFKS at three months in study I which changed towards a significantly improved level of knowledge of HF at six months II (IG:12.8±1.7 vs. CG:12.1±1.9) with an 11% increase in IG and decrease by 1% in CG (p=0.05).

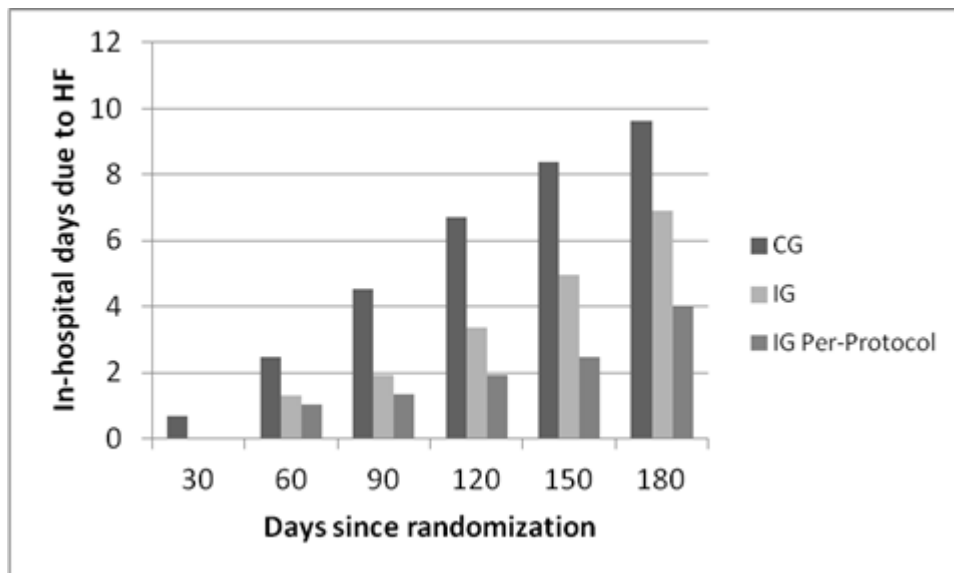
#### **10.1.5 Experiences and accessibility of mHealth**

In study II read information could be analyzed in the collected systems and demonstrated that persons who had used the mHealth system tended to actively choose to read topics that can be perceived as positive like “food and drink” whereas disease-oriented information were less likely to be studied.

Study III resulted in an identification of eight sub-categories that emerged from the 310 number of meaning units and they could all be united within “the specific theory of heart failure self-care”. We named the subcategories as adherence, support, obstacle, physical features indicating disease, psychological sensations, developing and using skills, independence and co-operation. These subcategories could be detected within the three main predefined categories in the theory, self-care maintenance, symptom perception and self-care management and developed an understanding of acceptability, perceived usefulness and potential areas of support.

#### **10.1.6 Hospitalization**

Hospitalization was measured with HF related days in hospital and decreased after three months in study I with 1.3 hospital days/person in IG vs. 3.5 in CG (RR 0.38; 95% CI:0.31-0.46; p=0.05). Follow-up with study II after six months demonstrated a significant reduction of HF related days in hospital by IG (RR:2.72, 95% CI:0.61-0.84, p=0,05) corresponding to a reduction of 2.7 days per patient over a six months period. In the IG there were 6.9 HF hospital days/ person vs. CG 9.6 HF hospital days/ person at six months (Figure 8).



Days	30	60	90	120	150	180
CG	0,7	2,48	4,53	6,71	8,38	9,63
IG	0,03	1,31	1,94	3,36	4,94	6,89
IG per-protocol	0,04	1,04	1,36	1,92	2,47	4,02

**Figure 8.** Hospitalization days due to heart failure for all persons who entered the study I and II during six months. Results from three months reprinted from Sc.Card.J with permission from Taylor & Francis. Results from six months are unpublished data.

# 11 DISCUSSION

## 11.1.1 Principal observations

The synthesis of this thesis showed that both the mHealth system and yoga enhanced and strengthened self-care and disease specific HRQoL. Persons with HF equipped with the mHealth system improved in self-care and experienced a better disease specific HRQoL together with a significant reduction of HF-related hospital days. These results sustained at six months follow-up together with an increase of disease specific knowledge. The adherence to the system was high. The invention mHealth system, was easy to use even for older persons with HF and improved self-care without increasing the burden on health care providers. The experiences of the mHealth system could be determined in relation to “the situation specific theory of heart failure self-care”. Technical adversities were considered an obstacle but not necessary a problem with a quick, easy technical support. Both yoga and hydrotherapy improved in exercise capacity, HRQoL and decreased anxiety and depression.

## 11.1.2 Comparison with previous studies

### *11.1.2.1 Self-care by mHealth and yoga*

Self-care is needed in maintenance and management of a disease such as HF. Self-care is known both to have an automatic response to action due to values and motivation self-care has also the possibility to be a learned. Looking at self-care from that aspect it can be improved by the increased use of mHealth but also through the effort of engaging in exercise like yoga and hydrotherapy. In the population of persons who have HF there are a lot of factors to consider when developing interventions to improve such an important process as self-care. Experiences, skills, motivations, habits, cultural beliefs and values, functional and cognitive abilities, confidence together with support and access to care, are all important and have their impact on self-care behavior (226). There are also other factors known to affect the interaction with self-care such as age, gender, depression, NYHA class, HRQoL, socioeconomic factors as well as education (16, 48). In previous RCT studies examining persons with HF and their self-care behavior, significant improvements have been detected between IG using mHealth in comparison to CG (63, 84, 85, 91, 93, 227). In this thesis there were support of some of these findings. In study I and II the self-care behavior through using the mHealth system increased both after three and six months when we measured by EHFS<sub>CB-9</sub>.

Through a development of habits and knowledge connected to maintenance together with the assistance from the mHealth system about how and when to act within self-care management,

there was a feeling of self-confidence growing through self-esteem expressed in study III. Further, a motivation of weighing together with understanding its importance was created, developing a habit of adherence to self-care. Previous studies indicate that functional capacity and knowledge directly are associated with self-care management but also that health literacy and social support are directly related to self-care maintenance. Moreover, self-care confidence mediates the relationships between knowledge, health literacy, social support and self-care behavior within HF (61). As such it maybe the interaction of social support from relatives and partners that may have had an impact on the adherence to self-care maintenance in study I and II. Anyhow the increased self-care confidence understood by the experiences of the persons used the mHealth could be a good foundation for both self-care maintenance and management. The impact seen by mHealth on self-care has also been reported in a recent review by Radhakrishnan with significant improvement in self-care behaviors such as daily weighing, medication management, exercise adherence, salt restriction and stress reduction. On the other hand five out of the 14 studies did not find any differences in self-care between IG and CG (228).

All studies conducted in this thesis clearly supported the self-care process from various aspects, using different scientific methods, as quantitative RCT studies but also with a qualitative approach with semi structured interviews. From a theoretical point of view the experiences with the mHealth system in connection to self-care in study III could be interpreted in line with “the situation specific theory of heart failure self-care”(43). The mHealth used in earlier studies in the literature were developed with technical connections between the persons home and the hospital. The mHealth system evaluated in this thesis seemed to offer something new in terms of accessibility together with the allocation of main responsibility for self-care to the person itself. The decision for actions was in the hand of the person or as a joint decision together with caregivers, when the mHealth system gave an indication to seek care. The system was designed in a way to make it easy to integrate in elderly persons daily lives and make them reflect over their condition with a direct response of suggested actions in case of deterioration. In study III experiences of performing something important true weighing was expressed. Their experiences of using the mHealth system with instructions on daily weight was vital and improvement in self-care management was developed possibly due to instant real-time instructions of how to manage a deterioration.

#### *11.1.2.2 HRQoL, anxiety and depression*

The measurements of HRQoL are dividing evaluation through generic instruments and disease specific instrument. As the disease specific instruments are constructed to measure specifically HRQoL within the HF population, a use of only those instruments would perhaps have been more adequate to solely use in this thesis. On the other hand, there is an association between higher PA levels and a better generic HRQoL (EQ5D-VAS) which implies that generic HRQoL might be possible to improve by adopting a physical active life style as in study IV. In HF there are known factors that influences around 50% of poor HRQoL outcome, among those are psychological distress, poor health perception, higher NYHA grading and lower education level (30). The possibility to offer a wider variety of training options includes exercises at home like performance of yoga in attempt to improve HRQoL. In study IV with yoga, significant improvements were seen with results from within the yoga group from pre-posttests in HRQoL with EQ-VAS together with the domains of symptom frequency, self-efficacy and both clinically and summary score of the disease specific questionnaire KCCQ. There was also significant improvement in depression within the yoga group in study IV which is known to be a significant predictor for outcomes in HF. Symptoms of depression have a considerable overlap with other symptoms and are sometimes difficult to detect. A recent meta-analysis observed the beneficial role of aerobic exercise training in persons with HF and relationship between depression and HF with respect to both epidemiology and pathophysiological aspects (73). Psychological distress should be considered in future efforts to address self-care and HRQoL in persons with HF (229). The results in study IV demonstrates significant differences from pre-to posttest in exercise capacity, depression, generic and disease specific HRQoL, reflecting a balance physically and mentally by yoga. Our findings are supported by a recent meta-analysis examining the effects of yoga compared to control with a positive impact of yoga on exercise capacity and HRQoL in persons with HF (188). Larger multicenter studies to generalize these results are needed to investigate what specific effects different parts of yoga are consisted. Although yoga shows benefit for persons with HF there is a lack of knowledge how yoga can support HRQoL in the best possible way.

#### *11.1.2.3 The mHealth system in aspect of adherence*

In this thesis the persons in study I and II had a high adherence of 85-88 % to the mHealth system. Measuring adherence can be considered from different aspects. Adherence to use a mHealth system is usually high around 70-90% (86, 87, 230). Depending on the type of mHealth system used and if the persons needs to rapport the self-care action e.g. weighing, medication intake etc. themselves through the system or if it is automatic, adherence can

vary. On the other hand, the adherence to the self-care advices proposed within mHealth systems in general, shows various results of adherence within the same self-care advice. A novel study evaluated an online education and coaching program to promote self-care that was automatically tailored to the knowledge and behavior of the person with HF. Self-reported self-care behavior in that study improved for daily weighing, low-salt diet and PA (231). There are other studies with short term adherence by three months with mHealth and weighing showing promising results (96, 145). Even though there are many barriers to optimal self-care it seems that adherence is usually high to self-care within mHealth.

There are many difficulties initiating and maintaining exercise training in persons with HF. Even if the persons are well informed of the importance of exercise there are many barriers to get across to perform regular training. It can be physical symptoms and lack of energy and the adherence to exercise beyond six months is low (7, 139). In study IV the adherence to both yoga and hydrotherapy was high. Everybody included in the analysis in study IV performed at least 20 sessions supervised yoga or hydrotherapy during the three months of intervention. Longtime results are known to decrease in adherence concerning PA (100).

Due to a higher shared HF knowledge and self-care adherence behaviors are more likely to be successful when persons with HF and their partners get information and support, the burden can be shared and the dyads can support each other (232, 233). This may also be a contributing factor to adherence to the mHealth system in our study, as 77% of the persons had a partner. In a review that examined 46 studies with both qualitative and quantitative design investigations with mHealth as part to support self-care. The use of mHealth could be identified as a solution for those living in rural areas and in remote places to provide access to specialized healthcare and self-care advices without frequent traveling. However, they demanded more comprehensive studies to strengthen education in self-care through technical support (234).

#### *11.1.2.4 Disease specific knowledge*

The instrument DHFKS measured knowledge in HF in general, symptom recognition and treatment. Ciere et al examined the effect of mHealth in a review consisting of 12 studies and found that increase in disease specific knowledge mediates improvement in HRQoL (98). To improve the development of knowledge to enhance self-care, detailed guidelines are now available (235). It is known that the perception of the complexity concerning the composition in the self-care process can differ. While the person with HF describes self-care regimen as hard work, the healthcare staff, may feel that the persons do not perform self-care even if the



instructions and actions are easy to perform. The persons with HF seem to need more knowledge with main emphasis on *how* self-care can be performed (236). Disease specific knowledge has been evaluated with the questionnaire DHFKS in concern to mHealth in a few RCT studies with an increase in level of knowledge in most of them (63, 90, 95, 96). On the other hand, not, everybody has found that knowledge increase using mHealth. Wakefield et al did not see any significant increase in level of knowledge (88). The disease specific knowledge in our studies I and II were also measured with the valid and reliably DHFKS instrument but nevertheless the disease specific knowledge measured high scores already at baseline and no significant differences after three months but a significant increase in knowledge at six months follow-up.

#### *11.1.2.5 Decrease in hospitalization with m-Health*

An important outcome in HF with mHealth is decrease of hospitalization and is highlighted in guidelines (4). To identify patterns of self-care behaviors in persons with HF and their association with clinical events is of great value. A recent prospective cohort study identified three patterns of self-care behavior, poor symptom response, good symptom response, and maintenance-focused behaviors. Patients with good symptom response behaviors had fewer clinical events compared with those who had poor symptom response behaviors. Persons with HF and poor symptom response behaviors had the most frequent clinical events (237). Therefore, it seems of highest importance that persons with HF learn how to manage their symptom deterioration. The result with decreased hospitalization in study I and II together with excellent adherence and positive experiences reported in study III with the mHealth system indicate a system with great potential for increased self-care.

#### **11.1.3 Strengths in this thesis**

In this thesis the greatest strength is the possibility to illuminate and explore the complicated self-care process and HRQoL from different aspects both with RCT studies I, II and IV together with experiences from interviews with persons who used the mHealth in study IV. The propositions made from Mays and Pope (238) was used to establish trustworthiness in the qualitative research in study III. To establish validity, reflexivity was described by personal characteristics like professional status of the interviewer. Negative cases with contradictory findings were highlighted. A clear exposition of the method of data collection and analysis was made, and interpretation was proffered adequately by support from the data. Sufficient data was collected from the persons interviewed to make saturation but also to make fair dealing with incorporation of a wide range of perspectives. In study IV the persons were on opti-

mal drug treatment and had been to an outpatient HF clinic with individually adjusted HF information when entering the study at baseline. Improvements in HRQoL and 6MWT on top of optimal treatment in both yoga and hydrotherapy strengthened the results. In study I and IV there was a random component in the sequence generation process such as sealed envelopes prepared by a third person in advance. That person was not involved in the research process and shuffled envelopes as a safeguard at allocation. Concerning internal validity in study I, II and IV all the instruments used was tested for validity and reliability and used in HF population. As a strength a power analysis was performed in study I and II. To deal with the drop-out issues, external validity was considered acceptable as findings and conclusions in study I and II were made with sufficiently large samples.

#### **11.1.4 Limitations in this thesis**

The persons included in this thesis were in different stages in their HF condition. In study I 40% of the study participants had de novo HF without proper levels of medication which could have had an impact on the improved results of the condition in HRQoL over time. Inclusion criteria in study IV had an upper age limit of 80 years, although persons with HF are very often older than 80 years. There was a dissimilarity at baseline in study I and II regarding atrial fibrillation which was more common in the CG and as atrial fibrillation is an important prognostic factor it could have affected the results. Hospitalization rate was not larger in the subgroup of atrial fibrillation and therefore it is unlikely that it had any impact on hospitalization results. Concerning generalization, the study population were small in study I and II and study IV was a pilot study, so they should be considered as such, and the results cannot be generalized to the entire HF population. In study III all 32 persons who had tried the mHealth received an invitation letter offering to share their experiences in an interview, but reasons for not participating were not asked and 17 persons came to share their experiences in an interview, which may have led to a positive selection. All the persons showing up for interviews had tried their best in being adherent to weighing. To optimize the reflexivity by avoiding influence of personal relation, a potential distance between person and interviewer was not considered. A triangulation in study III from the both the caregivers like partners and relatives but also the persons performing technical support of the mHealth system could have ensured comprehensiveness and encouraged a more reflective analysis of the data. The interviews were made after three months, thereafter the persons continued in the study for additional three months. This may of course have had an impact on evaluation of the six months result. More carefully gathering of background variables known as confounders concerning knowledge such as income and education levels could have gained a richer approach to some

of the questions raised in this thesis. The three months follow ups were made at the hospital in study (I, IV). At six months follow up in study II the questionnaires were sent home which may have affected the results. There was a lack of update of the mHealth system in study I and II both according to the change of guidelines that appeared during the study in fluid restriction and the dose of diuretics that was inscribed in the tablet only at the baseline. None of the studies were registered in any study base like for example “Clinical Trials.gov”.



## 12 CONCLUSIONS

- The synthesis of this thesis showed that both the mHealth system and yoga enhanced and strengthened self-care and disease specific HRQoL.
- Persons with HF equipped with the mHealth system improved self-care and disease-specific HRQoL after both three and six months without increasing the burden on health care providers. The adherence to use the mHealth system was high both at three and six months.
- A significant reduction of HF-related hospital days was observed after both three and six months.
- Increase in disease-specific knowledge expanded over time and gave a significant improvement after six months.
- The experiences of the mHealth system revealed insight in the importance of adherence to the self-care process through daily weighing. The importance was enhanced by the repeated reminder and instant feed-back from the mHealth-system and strengthened the feeling of safety and self-confidence together with a deeper understanding of cause and effect in self-care. The mHealth increased self-care maintenance and disease specific knowledge through understanding deteriorating symptoms and signs in connection to weight change with suggestions of self-care management.
- Experiences of technical adversities were considered an obstacle with mHealth but not necessarily a problem with quick and easy technical support.
- The experiences of mHealth could be determined in relation to “the situation specific theory of heart failure self-care”.
- Yoga and hydrotherapy had equal effect on HRQoL in persons with HF. Both yoga and hydrotherapy improved exercise capacity and decreased anxiety in persons with HF. Yoga was well tolerated and could be an alternative or complement to traditional forms of exercise training in HF.



## 13 FUTURE PERSPECTIVES

This thesis has generated new questions and ideas for future research and inventions about self-care among persons with HF. All the studies performed in this thesis was relevant in adding new knowledge in the area.

- Develop mHealth and test interventions together with yoga.
- Develop and test a yoga model or theory for persons with HF.
- Further explore how to support partners in the area of mHealth.
- Further explore the cognitive effects but also depression and anxiety within yoga.
- Develop new instrument for measurement of yoga in HF.
- Gender perspective concerning HF and yoga to enhance self-confidence.
- Evaluation of hospitalization in larger multicentered trials are needed with yoga in HF population.
- Health-economic evaluation of cost-effectiveness is needed in larger populations with mHealth.





## 14 SAMMANFATTNING (SUMMARY IN SWEDISH)

Hjärtsvikt påverkar mer än 38 miljoner människor världen över idag och det är extremt viktigt att stärka deras egenvård. I Sverige är den totala förekomsten av hjärtsvikt ca 2–3%.

Hjärtsvikt drabbar främst äldre och medelåldern är 75 år och över 80 års ålder kan ca 10–20% av befolkningen ha utvecklat hjärtsvikt. Två procent av Sveriges totala sjukvårdskostnader är relaterade till hjärtsvikt och 75 % av kostnaderna orsakas av sjukhusvistelse. Egenvård innefattar en beslutsprocess som både är förebyggande för hälsan och hanterande av kronisk sjukdom, med kärnelement som egenvårds-beslut, egenvårds-övervakning, och egenvård-hantering. Det anses vara av yttersta vikt vid kronisk sjukdom och både nationella och internationella riktlinjer ger tydliga rekommendationer för egenvård vid hjärtsvikt. Idag i samhället finns en trend mot ökad användning av teknik i olika former som exempelvis mHealth för att stärka egenvården. Inom mHealth-konceptet är telemonitorering en del som övervakar försämring av sjukdomstillstånd med eller utan överföring av fysiologiska data. Mycket talar för att mHealth påverkar sjuklighet och dödlighet, men också förbättrar egenvård och livskvalitet. Det gäller även egenvård med fysisk aktivitet och träning där fördelarna är väl dokumenterade. Fysisk träning vid hjärtsvikt är inte bara säker utan också associerad till minskad risk för sjukhusvistelse, minskad dödlighet samt ökad livskvalitet. Det finns stort intresse och stor potential att förbättra och intensifiera egenvårdsprocessen hos personer med hjärtsvikt, tex nya fysiska träningsmetoder som är individualiserade och baserade på personliga preferenser. Syftet med denna avhandling var att beskriva erfarenheter och utvärdera effekterna av nya metoder för att stödja egenvården genom ett mHealth system och yoga hos personer med hjärtsvikt.

I studie I utvärderade vi ett nytt mHealth system bestående av en specialiserad programvara i en pekplatta som var trådlöst ansluten till en våg. Pekplattan innehöll förutom livsstilsråd för personer med hjärtsvikt enligt gällande riktlinjer också aktuell föreslagen dos av diuretika samt förändringar i vikt och livskvalitet över tid. Personer med hjärtsvikt (n=82) randomiserades från tre sjukhus till kontrollgrupp eller att använda mHealth systemet i tre månader. Studien visade en signifikant ökad egenvård, hälsorelaterad livskvalité samt minskade sjukhusdagar pga. hjärtsvikt för de som använde mHealth systemet.

I studie II utvärderades mHealth systemet i samma population efter sex månader. Syftet var att utvärdera långtidseffekter och det visade fortsatt signifikant förbättrad egenvård, hälsorelaterad livskvalitet och minskade sjukhusdagar. Långtidsuppföljningen visade även ökad kunskap om hjärtsvikt.

I studie III utforskades erfarenheterna hos 17 personer med hjärtsvikt som hade använt mHealth systemet i tre månader. En kvalitativ studiedesign med halvstrukturerade intervjuer analyserades deduktivt med en teoretisk grund från "the situation specific theory of heart failure self-care". Intervjuerna speglade erfarenheterna av vägning, intag av diuretika med och genom påminnelser i mHealth systemet och på så sätt stärktes egenvården hos personer med hjärtsvikt. Erfarenheterna av mHealth systemet kunde sammankopplas med den teoretiska basen i "the situation specific theory of heart failure self-care". Tekniska motgångar i vågen och pekplattan ansågs vara ett hinder med inte ett problem eftersom det fanns snabb teknisk support.

I studie IV undersökte vi om yoga och hydroterapi hade samma effekt på hälsorelaterad livskvalitet hos personer med hjärtsvikt. Vi jämförde också effekter på träningskapacitet, kliniska resultat, ångest och depression. Totalt 40 personer randomiserade till tre månader med träning av yoga eller med hydroterapi två gånger i veckan. Yoga och hydroterapi hade lika stor inverkan på livskvalitet, träningskapacitet, kliniska utfall, ångest och depression med förbättring i bägge grupperna. Inom yogagruppen sågs signifikanta förbättringar gällande hälsorelaterad livskvalitet samt att depression minskade. Inom hydroterapigruppen förbättrades muskelstyrkan i de nedre kroppsdelarna signifikant.

### Sammanfattning

Personer med hjärtsvikt som fick stöd i egenvård genom mHealth systemet visade ökad egenvård, hälsorelaterad livskvalitet samt minskat antal sjukhusdagar efter tre och sex månader. Efter sex månader hade också sjukdomsspecifik kunskap förbättrats. Följsamheten till vägning och justerat intag av diuretika var genomgående bra med m-Health systemet och erfarenheterna kunde kopplade till teorin "the situation specific theory of heart failure self-care". För att öka hälsorelaterad livskvalitet och minska depressiva symtom hos personer med hjärtsvikt kan yoga vara ett alternativ eller komplement till etablerade former av fysisk träning.

## 15 ACKNOWLEDGEMENT

I want to express the deepest gratitude to everyone who contributed in any way or supported me throughout the creation of this thesis.

*My thoughts go particularly to:*

**All persons suffering from heart failure** and their partners. You have all been my source of inspiration in dedication of your time and effort to do the best in the randomized interventions assigned to you. Also, sharing your experiences and thoughts through interviews and questionnaires, even if you were troubled with suffering of symptoms and signs of sickness. My belief and hope that this thesis will create some positive seeds for the future in HF self-care.

**My mental teachers** Ven.Kalu Rinpoche and Ven.Lama Ngawang showing and teaching me methods of developing patience, wisdom and compassion towards all sentient beings.

*Also, all of you who made this become a thesis, especially:*

**Inger Hagerman** MD, PhD, my excellent most respected and valuable main supervisor. My gratitude is not enough to describe your skill, knowledge, support and great wisdom that you have shared with me. Your guidance in the research process as well as in real life has always been inspiring and constructive. Thank you for all the time you have shared instantly, and I hope that our developed invaluable friendship will continue in the future.

**Anna Strömberg** RN, PhD and professor, my generous, experienced and skilled co-supervisor. Thank you for your invaluable contributions to this thesis and your great guidance. The support with your research expertise and heart failure self-care knowledge has been inestimable. You have with a great tribute making significant research time possible. Thank you, Anna, for having patience with my ignorance in the research process!

**Patrik Lyngå** RN, PhD, my enthusiastic co-supervisor. Thank you for being you with your positive, engaged, great interest and always being easy available in our cooperation with confidence and trust. Also, for your kindly persistent prompting me into doing qualitative research. Your ambition to do right is strong.

**Carina Carnlöf** RN, MSN, PhD my mentor and nearest neighbor at work. Thank you for your time in daily issues and discussions about life's ups and downs. Now we soon passed over the bridge and we both are about to crack the hard nut of the thesis! Wish you all the best for the future and hope our friendship will continue and be strong.

**Research committee and opponent** Thank you for devoting your time and sharing great knowledge! **Inger Ekman, Mai-Lis Hellénus, Åsa Dederling, Britt Östlund, Karin Schenk-Gustafsson.**

**Göran Boll**, and yoga instructor colleagues for your amazing dedication and generosity and time of bringing the science of yoga at light. Thank you Göran, I hope in the future to be able to work together with you again and share knowledge and experience from your broad mind and great generosity of positivity!

**Andreas Blomqvist and Fredrik Westman** CareLigo, for help and interest to visualize, create, and implement together with me a technology as a home-based mHealth tool for persons suffering from heart failure with motivation to make him/her an active part in self-care. Thank you!

Physiotherapists **Kerstin Dencker and Ulrika Lennmark** and colleagues, for your diligent and thorough invaluable help with many physical tests for many long years and the performance of the exercises in hydrotherapy groups.

**Sören Björkman** my dear husband, best friend and life partner you are my steady mountain, thank you for helping me in many practical ways to perform this thesis.

As valuable as my right and left eye. My dearest son **Andreas Hägglund** thank you for your time and effort of assistance and our discussions about statistics. My dearest daughter **Linnea Björkman** for helping and being by my side. Thank you both for your interest in science and invaluable support in hard times being my greatest joy in this life! **Mira Hägglund** you have been my breathing space and broadened my views with new ideas and funny remarks. You are my diamond treasure!

**My management chef's and dear working colleagues** at the cardiac clinic at Karolinska University hospital, Huddinge, Sweden for your willingness and collaboration to create opportunities to pursue clinical practical research over many long years. You have **all contributed** directly or indirectly to the creation of this thesis which has the aim to help persons with heart failure to a better development in the self-care process. Thank you all!

**Research nurses Birgitta Wehlin-Berger, Gunilla Förstedt and Eva-Lotta Nylund** for your open and cordial benevolence to help in research and science.

**Irene Saviaro** and all the secretary colleagues and chefs for your beautiful happy laughter's and humble attitudes to serve and help in times of difficulty. Thanks also for being my guinea pigs in developing my skills as a yoga therapist!

**Library staff**, faculty of health sciences, Karolinska University, Huddinge most humbly thanks to you all for your services throughout the years. You are all a great instance of knowledge.

**My co-authors** for sharing your skills in scientific writing and akribi.

**My parents**, thank you for creating a stable ground in life with love, care and understanding. You will always be in my heart as a part of me.

**My dear brother and sister together with closest friends**, thank you all for being there for me in sickness and health, in success and sorrow and sharing this short life. Thank you, dearest brother, for walking beside me all the way as the most valuable friend.

**My girlfriends** "cow release" thank you for all the laughter and sharing pleasures in life.

The studies of this thesis were financially supported by grants and scholarships from the **Heart and Lung foundation, Swedish National Quality registry of Heart failure (RiksSvikt), CareLigo system, Karolinska University Hospital, Medical Research Council of Southeast Sweden.**



## 16 APPENDIX 1

### Program 1

Keep your eyes closed all through the set and focus on a point between the eye brows (3rd eye). Use a mental mantra: SAT NAM, Sat on the inhale and Nam on the exhale. Tune in before the set and tune out after the set.

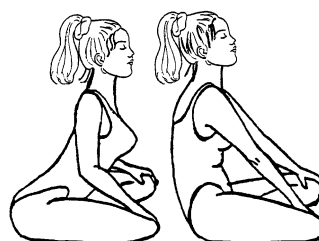
#### 1. Corps Pose – Long deep breathing

Lie flat on your back, Relax and do long deep breathing through your nose. 5-11 minutes.



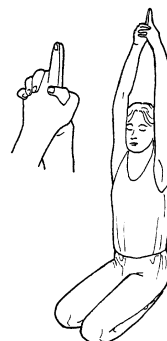
#### 2. Spine Flexing

Sit with your legs crossed and a straight spine, hold on to your ankles. Start flexing the spine back and forth, slowly, inhaling going forward, exhaling going backwards. 3-5 minutes. End with contraction of the muscles around the anus, urinary tract and navel-(Rootlock). Relax.



#### 3. Sat Kriya

Sit on your heels, spine straight, interlace your fingers, extend your index fingers pointing upwards. Stretch your arms above your head no bend in the elbows, upper arms hugging your ears. Say out loud the mantra *Sat* squeezing the navel and a full Rootlock. Say *Nam* as you relax and release the belly, let the breath come naturally. 3 minutes. Relax.



#### Meditation - Guru Ram Das

Sit cross legged, the palms of your hand against the heart, the left hand inside the right. Focus on your heart and repeat the mantra: Guru Guru Wahe Guru, Guru Ram Das Guru. (the wisdom that comes as a servant of the Infinite), 7-11 minutes. End the set.



### Program 3

Perform the exercises slowly and gently. The practicing should never cause pain. Inhale through the nose, mentally vibrate the mantra SAT, Exhale through the nose, vibrate NAM. Long slow breathing. Keep your eyes closed through the set.

**1. Breath of Fire.** Spine straight. Arms up 60 degrees. Inhale and exhale with short rapid movements in the stomach. 1 minute. Rootlock. Take your arms down. Relax.



**2. Spine Flex** Spine straight. Move it forward with hands on your knees, inhale, Exhale when you flex backwards. 1-3 minutes. End with Rootlock. Relax.



**3. Spine Twist.** Hands on your shoulders. Fingers forward and thumbs down the back. Elbows out to the sides. Inhale, twist to the left. Exhale, twist to the right 1-3 minutes. Relax.



**4. Side Bending.** Hand in the same way as in exercise nr 3. Inhale and bend sideways down to the left, exhale over down to the right. 1-3 minutes. Relax.



**5. Neck Roll.** Spine straight, start rolling the neck, slowly, clockwise. Ten laps. Reverse and roll it counter clockwise another ten laps ***Make sure there is no pain in the neck during the exercise.*** Then, sit straight up and relax 3-5 minutes with your eyes closed



### Meditation

Sit in a comfortable position, spine straight, eyes closed, focus in your 3rd eye point between your eye brows. Left hand in your lap, there press thumb against forefinger. Lift your right hand to your face. Press your right thumb against your right nostril, inhale through your left nostril. Hold. Now move the forefinger on your right hand and press it against your left nostril, at the same time release the thumb. Exhale through your right nostril. Switch back again so that you inhale through your left nostril and exhale through your right nostril. Keep this up for 11 minutes, then rest.





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